HEALTH AND SAFETY ASPECTS OF THE USE OF MECHANICALLY DEBONED MEAT

Volume II. Background Materials and Details of Data

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PREFACE

This volume is a companion to the document "Health and Safety Aspects of the Use of Mechanically Deboned Meat, Volume I--Reports and Recommendations of the Select Panel." Included in Volume II are copies of the legal documents which were issued concerning use of mechanically deboned meat; information on the selection of samples of MDM, results of analyses of the samples, and methods of analysis used; data on projected consumption of MDM and minerals it contains; and summaries of meetings of the Select Panel.

The materials in this volume are for the use of those persons needing more detailed information than was presented in Volume I. Details of unpublished methods of analysis and other unpublished citations listed in Volumes I and II are available on request.

As an aid to the readers, the Table of Contents for Volume I has been included in Volume II.

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HEALTH AND SAFETY ASPECTS OF

THE USE OF MECHANICALLY DEBONED

MEAT (MDM)

Volume I FINAL REPORT AND RECOMMENDATIONS OF THE SELECT PANEL

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APPENDIX I
PROPOSED REDEFINITION OF MEAT

Animal and Plant Health Inspection Service

[9 CFR Parts 301, 317, and 319]

DEFINITION OF MEAT AND CLASSES OF MEAT, PERMITTED USES, AND LABELING REQUIREMENTS

Notice of Proposed Rulemaking

• *Purpose:* The primary purpose of this document is to propose amending the meat inspection regulations to revise the definition of meat and provide for uses and labeling of certain classes of meat. •

Notice is hereby given in accordance with the administrative procedure provisions in 5 U.S.C. 553, that the Animal and Plant Health Inspection Service of this Department is considering amending Parts 301, 317, and 319 of the meat inspection regulations (9 CFR Parts 301, 317, and 319), under the Federal Meat Inspection Act, as amended (21 U.S.C. 601 et seq.), to revise the definition of "meat", to define certain classes of meat, to provide for the labeling of such classes of meat in products, to provide for the use of certain classes of meat in products, and to specify limits with respect to fat and certain classes of meat in products.

Statement of Considerations: There is an ever increasing strain placed upon the world's available food supply. Materials which were not traditionally used as foods in certain parts of the world are now gaining wide acceptance. Inflation, plus the increased competition for available supplies, are but two of the many economic factors interacting to raise the consumers' costs for food. The problem has triggered an all out search for new food sources, better utilization of existing sources, and means of reducing waste of available materials. Evidence to support the concern over serious shortages may be seen in the efforts of all nations to address the problem, and the scientific and technical resources committed to find answers.

The meat industry has recently utilized new nonmeat materials by combining them with traditional meat ingredients to process new products that are appealing to the consumer. In addition to using new sources of ingredients, the industry is also striving to develop new methods for recovering additional nutrients. Recently, mechanical equipment has been developed to a point where indications are that an additional 5 to 15 pounds of product containing 10 to 15 percent by weight of protein can be recovered from carcasses which undergo traditional hand deboning operations. More attention, too, is being placed on recovering the small amounts of protein occurring in fatty tissues. Both of these products are presently being produced and utilized in limited amounts under special guidelines developed by USDA for the purpose of acquiring factual data upon which to base this proposed rulemaking.

The Department wholeheartedly supports the effort to expand the food supply, but is conscious of its responsibilities as a regulatory agency in the field of meat and poultry inspection. The first consideration in allowing the use of any ingredient, new or traditional, is its wholesomeness. Secondly, the Department is becoming increasingly aware of its responsibilities in the field of nutrition. Meat and poultry are acknowledged as among the best sources of the complete protein needed by humans. To allow broad substitution of new products, which are wholesome and edible but greatly inferior to the traditional nutritional value of meat, would not serve the needs of the consumer. Although there may be cost benefits available, they must be carefully weighed against the public welfare and the need for adequate nutrition over a lifetime. This philosophy underlies the regulatory proposals regarding new types of meat products being recovered or processed by advanced technological methods.

What is meat? For many years the Federal meat inspection regulations (9 CFR 301.2(tt)) have defined meat as follows:

"*Meat.* The part of the muscle of any cattle, sheep, swine, or goats, which is skeletal or which is found in the tongue, in the diaphragm, in the heart, or in the esophagus, with or without the accompanying and overlying fat, and the portions of bone, skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing. It does not include the muscle found in the lips, snout, or ears. This term, as applied to products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats."

In preparing to revise the definition of meat, the Department first examined the two principal forms in which the consumer purchases meat. One form is essentially unprocessed, except for the cutting or grinding operation; e.g., steaks, roasts, chops, or hamburger. The second form is in processed products in which the meat ingredients are mixed with other ingredients of animal and/or vegetable origin to form a new product; e.g., various types of sausages and luncheon meat; canned products, such as stews and chilis; frozen products, such as pizzas; entrees, such as beef and gravy; and specialty foods, such as egg rolls.

Livestock carcasses and parts therefrom of lower grades are rarely used for retail cuts. It should be emphasized that by lower grades, we are referring to carcasses and parts therefrom which are wholesome in all respects, but which came from animals that because of age, type of feed, or length of time on feed, or other factors, yield carcasses and parts therefrom which are of lower quality. Such lower grade carcasses and parts therefrom are usually deboned completely. Meat derived from such animals, which is usually very low in fat content, and those trimmings derived from the production of retail cuts, which are usually much higher in fat content, are the meat ingredients frequently used for processed meat products.

These meats which are used for further processing form the large body of products known generally as manufacturing meat. The consumer never sees these meats as such, and the various processors usually produce or specify the types of trimmings they want for blending and processing into their line of products. However, new sources of manufacturing meat are now available as a result of advancing technology, principally in the area of low temperature rendering, high temperature rendering, and mechanical deboning. It is in order to allow wider use of these new products, that the Department proposes to expand the definition of the word "meat." Implicit in the proposed new standards is an assurance to the consumer that their inclusion in formulated products will not dilute the nutritional quality normally and traditionally associated with meat. This philosophy was discussed conceptually on March 22 with an Ad Hoc group of consumer representatives called together by USDA. Those attending were: Nancy L'Heveellyn—Member, Arkansas State Consumer Task Force, and Vice Chairman, Board of Directors, West Arkansas Community College; Camille Haney—Director of Consumer Affairs for Barkin, Herman, Solochick, and Paulsen, and Member, President's Consumer Advisory Council; Sue Kappler—Virginia Conference of Consumer Organizations; James Turner—Swankin, Turner, and Koch (Law Firm), and General Counsel, National Consumers League; Kinsey B. Green—Executive Director, American Home Economics Association; Harold Sherman—New York City Department of Consumer Affairs; Mitchell King—National Consumers Congress; Rodney Stein—State Department of Consumer Affairs, California; Martin Peterson—Director, External Liaison, Office of Consumer Affairs, Department of Health, Education, and Welfare; and Howard Seltzer—Deputy Director, Program Development and Implementation, Office of Consumer Affairs, Department of Health, Education, and Welfare.

While there was general agreement that nutritional standards for these products were a needed and progressive step, there was also, general concern as to how they would appear on the ingredient statement of a processed product. Consumers present at the meeting expressed reservations about the terms "Beef" and "Pork" (which are designations for hand-deboned meat) being appropriate for the products under consideration in this proposal. In their view, the processing required to produce the product altered the general nature of the products processed so that it should be identified in a more specific manner. Much of their concern centered about increased bone content which is discussed further in the Statement of Considerations, and controlled by the proposed standard for calcium. Several present suggested labeling terminology that would be descriptive of the processing technique, e.g., mechanically deboned meat and partially defatted meat. Their consensus was that consumers want sufficiently distinctive labeling upon which to base purchasing decisions between dif-

fering products and their respective prices.

Because of the reservations expressed by the Ad Hoc consumer group, the Department wishes to highlight this matter to all who plan to comment, and to expressly ask for information, data, views, or suggested alternatives to aid in reaching a final conclusion.

In responding to consumer concerns that nutritional standards are needed for these products, the Department is addressing three main points; the amount of fat, the amount of protein, and the quality of the protein.

Meat purchased as steaks, chops, or roasts by the consumer presents no problem with respect to the protein quality being artificially changed, and the amount of fat in such meat can be seen and considered in light of different trimming practices and price.

There could be a problem, with respect to the nutritional quality of products recovered by the mechanical deboning, or low or high temperature rendering operations. In order to allow the wider use of these products, the Department proposes to expand the definition of meat and include requirements that will assure the consumer that inclusion of these articles in formulated products will not dilute the nutritional quality traditionally associated with such products. Additionally, such requirements will allow identification of these various forms of manufacturing product so that a processor can avail himself of the types best suited to his finished products.

In recent years, the question of fat percentages in meat products is one which has generated a great deal of interest on the part of consumers. Fat is interspersed in the lean muscle tissue and also occurs as an overlying cover of whole muscles or muscle groups. Fat is also deposited in relatively large amounts in other parts of the carcass, such as around the kidneys or in other parts of the abdominal cavity, and is ordinarily processed into lard or tallow. Only that fat which accompanies and overlies the muscle would be included in the revised definition of meat. Many cuts of meat, both wholesale and retail, contain in excess of 50 percent fat; and some, such as pork jowls, contain approximately 85–90 percent fat. The consumer who is concerned about fat in the diet can select those cuts of meat which are known to contain lesser amounts of fat, or can trim away the overlying layer of fat to fit personal preference.

The incorporation of manufacturing meat of high fat content into meat food products has been the subject of many comments and much misunderstanding. It has been noted that in the preparation of carcasses, and wholesale and retail cuts, trimmings are produced which are used as ingredients in processed products. These are bought and sold on the basis of lean to fat content; "50–50" trimmings, for example, will average 50 percent lean and 50 percent fat. The production of these trimmings will frequently result in some pieces which contain very little lean or no lean at all, and other pieces which contain a high percentage of lean. One of the questions addressed by this proposal is whether to allow blending of such trimmings, or to require each piece to contain a certain amount of lean muscle tissue. The Department proposes that the control of the amount of fat in the finished product is the important consideration, and accordingly proposes to allow the blending of all trimmings, so long as there is a fat limit on the finished products.

With the multitude of processed meat items available, which have traditionally been made, sold, and found acceptable at various fat levels, an attempt to limit the use of ingredients by setting maximum fat levels for all products would be too cumbersome to be practical. Therefore, the Department proposes to divide certain classes of manufacturing meat into categories based, among other things, on fat levels with which they have been associated impose a 50 percent maximum fat limit based on the meat, meat byproduct, and poultry product content of all meat food products not otherwise specifically regulated as to fat content.

Aside from the question of fat, and protein quantity and quality, there are other considerations in the defining and acceptance of meats produced by new processes. In the mechanical deboning process, the bones are finely broken and some pulverized portions are incorporated into the product. There are two matters worthy of consideration in this respect. One is that of adulteration. Is the product adulterated by the presence of such bone? It is the Department's present, position that the bone, if present in such a particle size or in such an amount as to be readily apparent to the taste or touch, would indeed be identifiable as bone and would be a reason for considering the product to be adulterated. However, modern equipment can minimize the particle size and level of bone to an extent that it cannot be detected by sensation in the mouth Additionally, a trained taste panel was used to determine at which levels bone becomes apparent to the taste and thus objectionable. The members were unable to detect a significant taste difference between products prepared without the addition of mechanically deboned meat and products prepared with the addition of mechanically deboned meat containing calcium (which is an indicator of bone content) even at levels above those being proposed in this document.

To address another important consideration of the bone question, we should consider the place of calcium in the American diet. Concern has been expressed over maintenance of the calcium-phosphorous balance in the diet. The concern has been that the amount of calcium present is too low, and meat is one of the diet staples that is deficient in calcium. Calcium is one of the main constituents of bone, and that which is incorporated into mechanically deboned meat is readily available to the human digestive system and, therefore, should be considered in view of such concern. As long as the particle size can be controlled, and the amount incorporated into finished product not detectable in any way, the Department is of the opinion that far from being objectional, the presence of additional calcium may be of benefit.

Another product addressed by the proposal is that resulting from the low temperature rendering of meat tissues. Heretofore, if the starting ingredients were meat trimmings containing at least 12 percent lean meat, the finished product, after removal of most of the fat, was identified as "partially defatted chopped beef (or pork)." If the inital ingredients were trimmings containing less than 12 percent lean, the finished product was identified as "partially defatted beef (or pork) fatty tissue."

Much controversy arose over the use of these products in various processed meat products. Their nutritional value was questioned, and their status as meat or meat byproducts never completely resolved. Again, the Department proposes to adopt the nutritional quality approach and define these products as meat, provided they conform to the nutritional parameters set forth in the proposal. The parameters are such that the controversy over their nutritional quality should no longer exist to bar their use in appropriate products.

A calcium level has been set for these rendered products, since the renderer may use mechanically deboned parts of carcasses which exceed the calcium limits set for mechanically deboned meat.

High temperature rendering can produce meat with the same qualities as that produced by low temperature rendering, except that the product is cooked.

Although the lean muscle tissue of cheeks, heads, diaphragms, hearts, tongues, and esophagi have always been officially considered as meat, the Department has not always required explicit declaration of the presence of such tissue on labeling of products containing such tissues. For consistency, this proposal would permit these tissues to be used as meat without further labeling qualifications.

Because of the extent of the proposed amendments, the most important changes are summarized in tables following the proposal. Table 1 lists proposed fat, PER (or amino acid content), protein and calcium limits for the various classes of meat; and Table 2 lists certain standardized products and the classes of meat which would be permitted as ingredients in such products.

The proposed amendments are as follows:

1. § 301.2(tt) (9 CFR 301.2(tt)) would be revised to read as follows:

§ 301.2 Definitions.

* * * * *

(tt) Meat. Any edible portion of the carcass of any cattle, sheep, swine, or goats, exclusive of lips, snouts, ears, caul fat, leaf fat, kidney fat, and other visceral fat, and exclusive of all organs, *except* the heart, tongue, and esophagus;

and including but not limited to the following classes of meat: [1]

(1) Skeletal meat,
(2) Heart meat,
(3) Tongue meat,
(4) Esophagus meat,
(5) Meat trimmings,
(6) Fatty meat trimmings,
(7) Mechanically deboned meat,
(8) Mechanically deboned meat for processing,
(9) Mechanically deboned meat for rendering,
(10) Rendered meat,
(11) Rendered meat for processing,
(12) Cooked rendered meat, and
(13) Cooked rendered meat for processing.

The term "meat," as applied to products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

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2. § 317.2(f)(1) (9 CFR 317.2(f)(1)) would be amended by adding a new subdivision (vi) to read as follows:

§ 317.2 Labels: definition; required features.

• • • • •

(f)(1) • •

(vi) The terms "beef", "pork", "mutton", or "goat" (or "chevon") may be used for any of the classes of meat defined in § 319.5 of this subchapter when derived, respectively, from cattle, sheep, swine, or goats (chevon).

• • • • •

3. A new § 319.5 would be added to Part 319 to read as follows:

§ 319.5 Definitions of classes of meat.

Class 1: *Skeletal Meat*—skeletal muscle tissue with accompanying fat that has been attached directly to bone, including that from the diaphragm, and cheeks after they are trimmed to remove glandular tissue.

Class 2: *Heart Meat*—the heart trimmed of bone and cartilage.

Class 3: *Tongue Meat*—the tongue trimmed of cartilage and glandular materials.

Class 4: *Esophagus Meat*—the muscular portion of the esophagus.

Class 5: *Meat Trimmings*—the product resulting from the trimming of dressed carcasses, primal parts, or wholesale or retail cuts of skeletal meat, and containing 30 percent fat or less.

Class 6: *Fatty Meat Trimmings*—the product resulting from the trimming of dressed carcasses, primal parts, or wholesale or retail cuts of skeletal meat, and containing more than 30 percent fat.

Class 7: *Mechanically Deboned Meat*—the product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle tissue, and containing a minimum of 14.0 percent protein with a minimum Protein Efficiency Ratio (PER) value of 2.5 (or an essential amino acid content of 33%),[1] a maximum fat content of 30 percent, and a maximum calcium content of 0.75 percent.

Class 8: *Mechanically Deboned Meat for Processing*—the product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle tissue and which fails to meet one or more of the limits prescribed for class 7, but contains a minimum of 10.0 percent protein with a minimum PER value of 2.5 (or an essential amino acid content of 33%),[1] and a maximum calcium content of 1.0 percent.

Class 9: *Mechanically Deboned Meat for Rendering*—the product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle tissue and which fails to meet one or more of the limits prescribed for class 8.

Class 10: *Rendered Meat*—the product resulting from the partial removal of fat from meat of class 1, 2, 3, 4, 5, 6, 7, 8, or 9, or a combination thereof, by a low temperature (120° F. or less) rendering process, and containing a minimum of 14 percent protein with a minimum PER of 2.5 (or an essential amino acid content of 33%),[1] a maximum fat content of 30 percent, and, if mechanically deboned meat is used, a maximum calcium content of 0.75 percent.

Class 11: *Rendered Meat for Processing*—the product resulting from the partial removal of fat from meat of class 1, 2, 3, 4, 5, 6, 7, 8, or 9, or a combination thereof, by a low temperature (120° F. or less) rendering process, and which fails to meet one or more of the limits prescribed for class 10, but contains a minimum of 20 percent protein with a minimum PER of 2.0 (or an essential amino acid content of 28%),[1] a maximum fat content of 30 percent, and, if mechanically deboned meat is used, a maximum calcium content of 1.0 percent.

Class 12: *Cooked Rendered Meat*—the product resulting from the partial removal of fat from meat of class 1, 2, 3, 4, 5, 6, 7, 8, or 9, or a combination thereof, by a high temperature (160° F. or more) rendering process, and containing a minimum of 14 percent protein with a minimum PER of 2.5 (or an essential amino acid content of 33%),[1] a maximum fat content of 30 percent, and, if mechanically deboned meat is used, a maximum calcium content of 0.75 percent.

Class 13: *Cooked Rendered Meat for Processing*—the product resulting from the partial removal of fat from meat of class 1, 2, 3, 4, 5, 6, 7, 8, or 9, or a combination thereof, by a high temperature (160° F. or more) rendering process, and which fails to meet one or more of the limits prescribed for class 12, but contains a minimum of 20 percent protein with a minimum PER of 2.0 (or an essential amino acid content of 28%),[1] a maximum fat content of 30%, and, if mechanically deboned meat is used, a maximum calcium content of 1.0 percent.

4. A new § 319.6 (9 CFR 319.6) would be added to read:

§ 319.6 Limitations with respect to fat and certain classes of meat.

(a) Unless specific fat limits are otherwise prescribed in this Part for any products, the meat, meat byproduct, and/or poultry product portion of the formula shall consist of no more than 50 percent fat by analysis. This paragraph shall not apply to oleomargarine, margarine, mixed fat shortening, lard, leaf lard, and rendered animal fat or mixture thereof.

(b) In meat food products in which meat of class 8, 11, or 13, as defined in § 319.5, or a combination thereof, are permitted ingredients under this Part, the use shall be limited to a maximum of 20 percent of the total of all meat, meat byproducts, poultry products and poultry meat used in the formulation.

§ 319.15 [Amended]

5. Section 319.15(a) (9 CFR 319.15(a)) would be amended by inserting after the words "frozen beef in the first sentence the following: "only of class 1, 5, or 6, as defined in § 319.5 of this subchapter, or a combination thereof,"; by deleting in the first sentence the words "and without the addition of beef fat as such"; and by deleting the last sentence.

6. Section 319.15(b) (9 CFR 319.15(b)) would be amended by inserting after the words "frozen beef" in the first sentence the following: "only of class 1, 2, 3, 4, 5, or 6, as defined in § 319.5 of this subchapter, or a combination thereof,"; by deleting in the first sentence the following: "beef fat as such and/or"; and by deleting the last sentence.

7. Section 319.15(c) (9 CFR 319.15(c)) would be amended by inserting after the words "frozen beef" in the first sentence the following: "only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, or 11, as defined in § 319.5 of this subchapter or a combination thereof,"; by deleting in the first sentence the following: "beef fat as such and/or"; and by deleting in the second sentence the following: "and/or partially defatted beef fatty tissue".

8. Section 319.15(d) (9 CFR 319.15(d)) would be amended by deleting the remainder of the first sentence after the word "meat" and by inserting in lieu thereof the following: "only of class 1, 5, or 6, as defined in § 319.5 of this subchapter, or a combination thereof."; and by deleting the third sentence.

9. Section 319.15(e) (9 CFR 319.15(e)) would be amended by adding after the phrase "of fresh beef fatty tissue" in the first sentence the following: "and which does not meet the definition of meat class 10 or 11 contined in § 319.5 of this subchapter"; and by adding after the word

[1] Said classes of meat are defined in § 319.5 of this subchapter.

[1] The percent of the following amino acids expressed as a percentage of the total protein: phenylalanine, isoleucine, leucine, lysine, methionine, tryptophan, valine, and threonine. PER, if used, should be adjusted to 2.50 for casein.

"appearance" in the second sentence the words "and may be used wherever binders are permitted and at the same levels."

§ 319.29 [Amended]

10. Section 319.29(a) (9 CFR 319.29 (a)) would be amended by adding after the word "skin" in the first sentence the following: ", and which does not meet the definition of meat class 10 or 11 contained in § 319.5 of this subchapter"; and by adding after the word "appearance" in the second sentence, the words "and may be used wherever binders are permitted and at the same levels."

§ 319.80 [Amended]

11. Section 319.80 (9 CFR 319.80) would be amended by inserting after the word "shall" in the first sentence the following: "consist of meat only of class 1 or 5, as defined in § 319.5 of this subchapter, or a combination thereof, and shall"; and by adding a period after the words "surface fat".

§ 319.81 [Amended]

12. Section 319.81 (9 CFR 319.81) would be amended by deleting the second and third sentences; and by adding after the words "fresh beef weight" in the remaining sentence the following: ", and shall consist of meat only of class 1 or 2, as defined in § 319.5 of this subchapter, or a combination thereof".

§ 319.100 [Amended]

13. Section 319.100 (9 CFR 319.100) would be amended by inserting after the word "cuts" in the first sentence, the following: "of beef only of class 1, as defined in § 319.5 of this subchapter."; by inserting after the words "shall be prepared" in the second sentence, the following: "from beef only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, or 11, as defined in § 319.5 of this subchapter, or a combination thereof, and shall be prepared"; and by deleting the fourth and fifth sentences.

§ 319.104 [Amended]

14. Section 319.104(f) (9 CFR 319.104 (f)) would be amended by deleting in the first sentence the following: "may contain finely chopped ham shank meat to the extent of 25 percent over that normally present in the boneless ham"; and by inserting in lieu thereof the following: "shall consist of meat only of class 1 or 5, as defined in § 319.5 of this subchapter, or a combination thereof, derived from ham".

§ 319.105 [Amended]

15. Section 319.105(a) (9 CFR 319.105 (a)) would be amended by deleting after the words "prepared with" in the first sentence the following: "ham," and by inserting in lieu thereof the following: "meat only of class 1 or 5, as defined in § 319.5 of this subchapter, or a combination thereof, derived from ham, and with."

16. Section 319.105(b) (9 CFR 319.105 (b)) would be amended by deleting subparagraph (1), and renumbering subparagraphs (2) through (9) as subparagraphs (1) through (8), respectively.

§ 319.140 [Amended]

17. Section 319.140 (9 CFR 319.140) would be amended by deleting in the first sentence the words "kinds of meat or meat and meat byproducts" and by inserting in lieu thereof the following: "classes of meat or classes of meat and meat byproducts, as otherwise provided for in this subpart".

§ 319.141 [Amended]

18. Section 319.141 (9 CFR 319.141) would be amended by inserting after the comma following the words "or both" in the first sentence, the following: "of meat only of class 1, 5, 6, 7, 8, 10, or 11, as defined in § 319.5 of this subchapter, or a combination thereof"; by deleting in the first sentence the words "not including pork byproducts"; and by revising the second sentence to read: "The finished product shall not contain more than 45 percent fat, based on laboratory analysis."

§ 319.142 [Amended]

19. Section 319.142 (9 CFR 319.142) would be amended by inserting after the comma following the words "or both" in the first sentence the following: "of meat only of class 1, 5, 6, 7, 8, 10, or 11, as defined in § 319.5 of this subchapter, or a combination thereof"; and by deleting in the first sentence the words "not including beef byproducts".

§ 319.143 [Amended]

20. Section 319.143 (9 CFR 319.143) would be amended by inserting after the comma following the words "frozen meat" in the first sentence the following: "only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, or 11, as defined in § 319.5 of this subchapter, or a combination thereof"; by deleting in the first sentence the words "or meat and meat byproducts"; and by revising the second sentence to read: "The finished product shall not contain more than 45 percent fat based on laboratory analysis."

§ 319.144 [Amended]

21. Section 319.144 (9 CFR 319.144) would be amended by inserting after the word "swine" in the first sentence the following: "only of class 1, 7, or 8, as defined in § 319.5 of this subchapter, or a combination thereof,"; and by revising the second sentence to read: "The finished product shall not contain more than 45 percent fat based on laboratory analysis."

§ 319.160 [Amended]

22. Section 319.160 (9 CFR 319.160) would be revised to read: § 319.160 Smoked pork sausage. Smoked pork sausage shall conform to the provisions of § 319.141 of this subchapter, and shall be smoked with hardwood or other approved nonresinous materials.

§ 319.180 [Amended]

23. Section 319.180(a) (9 CFR 319.180 (a)) would be amended by deleting in the first sentence the words "one or more kinds of raw skeletal muscle meat or raw skeletal muscle meat" and by inserting in lieu thereof the following: "meat only of class 1, 5, 6, 7, 8, 10, or 11, as defined in § 319.5 of this subchapter, or a combination thereof, of such meat".

24. Section 319.180(b) (9 CFR 319.180 (b)) would be amended by deleting in the first sentence the following: "one or more kinds of raw skeletal muscle meat with raw meat byproducts, or not less than 15 percent of one or more kinds of raw skeletal muscle meat" and by inserting in lieu thereof the following: "meat only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, or 11, as defined in § 319.5 of this subchapter, or a combination thereof, with raw meat byproducts, or not less than 15 percent of such meat"; and by deleting the third sentence.

25. Section 319.180(e) (9 CFR 319.180 (e)) would be amended by inserting after the words "of this section" the following: "Partially defatted beef fatty tissue, partially defatted pork fatty tissue,"; and by changing the "D" to lower case in the word "Dried."

26. Section 319.180(g) (9 CFR 319.180 (g)) would be amended by deleting the remainder of the sentence after the comma following the word "tongues," and by inserting in lieu thereof the following: "lips, weasands, spleens, and visceral fat."

27. Subpart H was apparently deleted inadvertently (see 38 FR 14742). Therefore, subpart H would be added to read as follows:

Subpart H—Other Cooked Sausage

§ 319.200 Liver sausage and braunschweiger.

"Liver Sausage" and "Braunschweiger" are cooked sausages made from fresh and/or frozen pork and pork livers and/or beef livers and may contain cured pork, beef and/or veal. Such products shall, except as provided below, contain meat only of class 1, 5, 6, 7, 8, 10, or 11, as defined in § 319.5 of this subchapter, or a combination thereof. Liver sausage may also contain beef and pork byproducts; pork skins only of meat class 2, 3, or 4, as denfied in § 319.5 of this subchapter, or a combination thereof; and sheep livers and goat livers. These products shall contain not less than 30 percent liver computed on the weight of the fresh liver and may contain binders and extenders as permitted in § 319.140.

§ 319.260 [Amended]

28. Section 319.260 (9 CFR 319.260) would be amended by inserting after the words "comminuted meat" in the first sentence the following: "only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, or 11, as defined in § 319.5 of this subchapter, or a combination thereof."

§ 319.261 [Amended]

29. Section 319.261 (9 CFR 319.261) would be amended by inserting after the words "comminuted meat" the first sentence the following: "only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, or 13, as defined in § 319.5 of this subchapter, or a combination thereof."

§ 319.280 [Amended]

30. Section 319.280 (9 CFR 319.280) would be amended by revising the first sentence to read: "Scrapple shall contain not less than 40 percent meat and/or meat byproducts computed on the basis of fresh weight, and shall contain meat only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, or 13, as defined in § 319.5 of this subchapter, or a combination thereof."

§ 319.281 [Amended]

31. Section 319.281(a) (9 CFR 319.281 (a)) would be amended by deleting the period after the word "cooked" and by deleting the words "It contains meat"; and by inserting in lieu thereof the following: "and which contains meat only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, or 11, as defined in § 319.5 of this subchapter, or a combination thereof."

32. Section 319.281(b)(1) (9 CFR 319.-281(b)(1)) would be deleted and the remaining subparagraphs (2) through (9) would be renumbered (1) through (8)

§ 319.300 [Amended]

33. Section 319.300 (9 CFR 319.300) would be amended by inserting after the words "fresh meat" in the first sentence the following: ", and shall contain meat only of 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, or 13, as defined in § 319.5 of this subchapter, or a combination thereof"; and by deleting the second sentence.

§ 319.301 [Amended]

34. Section 319.301 (9 CFR 319.301) would be amended by inserting after the words "fresh meat" in the first sentence the following: ", and shall contain meat only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, or 13, as defined in § 319.5 of this subchapter, or a combination thereof"; and by deleting the second sentence.

§ 319.302 [Amended]

35. Section 319.302 (9 CFR 319.302) would be amended by deleting in the first sentence the words "and trimmed"; and by inserting after the words "cooked meat" in the first sentence the following: ", and shall contain meat only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, or 13, as defined in § 319.5 of this subchapter, or a combination thereof."

§ 319.303 [Amended]

36. Section 319.303 (9 CFR 319.303) would be amended by inserting after the words "with beef" in the first sentence of paragraph (a) the following: "only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, or 13, as defined in § 319.5 of this subchapter, or a combination thereof"; by deleting from paragraph (a)(1) the words "and trimmed"; by deleting subparagraphs (1) and (8) from paragraph (b); by renumbering subparagraphs (2) through (7) of paragraph (b) as subparagraphs (1) through (6), respectively; and by deleting paragraph (d).

§ 319.304 [Amended]

37. Section 319.304 (9 CFR 319.304) would be amended by inserting after the words "fresh meat" the following: ", and shall contain meat only of class 1, 5, or 6, as defined in § 319.5 of this subchapter, or a combination thereof".

§ 319.305 [Amended]

38. Section 319.305 (9 CFR 319.305) would be amended by inserting after the words "of the tamales" in the first sentence the following: ", and shall contain meat only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, or 13, as defined in § 319.5 of this subchapter, or a combination thereof"; and by inserting after the words "and gravy" in the third sentence the following: ", and shall contain meat only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, or 13, as defined in § 319.5 of this subchapter, or a combination thereof."

§ 319.306 [Amended]

39. Section 319.306 (9 CFR 319.306) would be amended by adding after the words "fresh meat" in the first sentence the following: ", and shall contain meat only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, or 13, as defined in § 319.5 of this subchapter, or a combination thereof."

§ 319.307 [Amended]

40. Section 319.307 (9 CFR 319.307) would be amended by adding after the words "fresh meat" the following: ", and shall contain meat only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, or 13, as defined in § 319.5 of this subchapter, or a combination thereof".

§ 319.310 [Amended]

41. Section 319.310 (9 CFR 319.310) would be amended by inserting after the words "and sauce" the following: ", and shall contain meat from the ham only of class 1 or 5, as defined in § 319.5 of this subchapter, or a combintion thereof, or bacon".

§ 319.311 [Amended]

42. Section 319.311 (9 CFR 319.311) would be amended by inserting after the word "ingredients" the following: ", and shall contain meat only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, or 13, as defined in § 319.5 of this subchapter, or a combination thereof".

§ 319.312 [Amended]

43. Section 319.312 (9 CFR 319.312) would be amended by deleting the words "and trimmed" in the first sentence; and by inserting after the words "cooked meat" in the first sentence the following: ", and shall contain meat only of class 1 or 5, as defined in § 319.5 of this subchapter, or a combination thereof."

44. The heading and text of § 319.313 would be revised to read as follows:

§ 319.313 Meat with gravy and gravy with meat.

"Meat with Gravy" and "Gravy with Meat" shall contain meat only of class 1 or 5, as defined in § 319.5 of this subchapter, or a combination thereof, and shall contain a minimum of 50 percent cooked meat and 35 percent cooked meat, respectively.

§ 319.500 [Amended]

45. Section 319.500 (9 CFR 319.500) would be amended by inserting after the words "uncooked meat" the following: ", and shall contain meat only of class 1 or 5, as defined in § 319.5 of this subchapter, or a combination thereof."

§ 319.600 [Amended]

46. Section 319.600(a) (9 CFR 319.600 (a)) would be amended by inserting after the words "raw meat" in the second sentence the following: ", and shall contain meat only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, or 13, as defined in § 319.5 of this subchapter, or a combination thereof."

§ 319.760 [Amended]

47. Section 319.760(a) (9 CFR 319.760 (a)) would be amended by inserting after the words "comminuted ham" in the first sentence the following: "only of class 1, 5, or 6, as defined in § 319.5 of this subchapter, or a combination thereof,"; and by revising the second sentence to read as follows: "The total fat content shall not exceed 35 percent of the finished product."

§ 319.761 [Amended]

48. Section 319.761 (9 CFR 319.761) would be amended by adding a new sentence at the end of the paragraph to read as follows: "Meat used for potted meat food product or deviled meat food product shall be meat only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, or 13, as defined in § 319.5 of this subchapter, or a combination thereof."

49. Section 319.762 (9 CFR 319.762) would be revised to read as follows:

§ 319.762 Ham spread, tongue spread, and similar products.

"Ham Spread", "Tongue Spread", and similar products may contain meat only of class 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, or 13, as defined in § 319.5 of this subchapter, or a combination thereof, and not less than 50 percent of the total meat used shall be of class 1, 2, 3, 4, or 5, or a combination thereof; computed on the weight of the fresh meat, and not less than 50 percent of the total meat used shall be of the meat ingredient of the product name.

Any person wishing to submit written data, views or arguments concerning the proposed amendments may do so by filing them, in duplicate, with the Hearing Clerk, U.S. Department of Agriculture, Washington, D.C. 20250, or if the material is deemed to be confidential, with the Product Standards Staff, Scientific and Technical Services, Meat and Poultry Inspection Program, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250, by August 25, 1976.

Any person desiring opportunity for oral presentation of views should address such request to the Staff identified in the preceding paragraph, so that arrangements may be made for such views to be presented prior to the date specified in the preceding paragraph. A record will be made of all views orally presented.

All written submissions and records of oral views made pursuant to this notice will be made available for public

inspection in the Office of the Hearing Clerk during regular hours of business, unless the person makes the submission to the Staff identified in the preceding paragraph and requests that it be held confidential. A determination will be made whether a proper showing in support of the request has been made on grounds that its disclosure could adversely affect such persons by disclosing information in the nature of trade secrets or commercial or financial information obtained from any person and privileged or confidential. If it is determined that a proper showing has been made in support of the request, the material will be held confidential; otherwise, notice will be given of denial of such request and an opportunity afforded for withdrawal of the submission. Requests for confidential treatment will be held confidential (7 CFR 1.27(c)).

Comments on the proposal should bear a reference to the date and page number of this issue of the FEDERAL REGISTER.

Done at Washington, D.C. on April 23, 1976.

F. J. MULHERN,
Administrator, Animal and Plant Health Inspection Service.

TABLE 1.

	MEAT CLASS	MAXIMUM PERCENT CALCIUM	MINIMUM PERCENT PROTEIN	MINIMUM PERCENT/ PERCENT ESSENTIAL AMINO ACIDS OR MINIMUM PER	MAXIMUM PERCENT FAT
SKELETAL MUSCLE	1	-	-	- -	-
HEART MEAT	2	-	-	- -	-
TONGUE MEAT	3	-	-	- -	-
ESOPHAGUS MEAT	4	-	-	- -	-
MEAT TRIMMINGS	5	-	-	- -	30
FATTY MEAT TRIMMINGS	6	-	-	- -	-
MECHANICALLY DEBONED MEAT	7	0.75	14	2.5 or 33	30
MECHANICALLY DEBONED MEAT FOR PROCESSING	8	1.00	10	2.5 or 33	-
MECHANICALLY DEBONED MEAT FOR RENDERING	9	-	-	- -	-
RENDERED MEAT	10	0.75	14	2.5 or 33	30
RENDERED MEAT FOR PROCESSING	11	1.00	20	2.0 or 28	30
COOKED RENDERED MEAT	12	0.75	14	2.5 or 33	30
COOKED RENDERED MEAT FOR PROCESSING	13	1.00	20	2.0 or 28	30

1/ Expressed as a percent of total protein

TABLE 2.

Reg. Cite in 9 CFR 319	PRODUCT NAME	CLASS OF MEAT 1	2	3	4	5	6	7	8	9	10	11	12	13
.15(a)	Chopped Beef, Ground Beef	x				x	x							
.15(b)	Hamburger	x	x	x	x	x	x							
.15(c)	Beef Patties	x	x	x	x	x	x	x	x		x	x		
.15(d)	Fabricated Steaks, etc.	x				x	x							
.80	Barbecued Meats	x				x								
.81	Roast Beef, Parboiled, Steam Roasted	x	x											
.100	Corned Beef Cuts	x												
.100	Canned Corned Beef	x	x	x	x	x	x	x	x		x	x		
.104(f)	Pressed Ham, Spiced Ham, etc.	x				x								
.105	Chopped Ham	x				x								
.141	Fresh Pork Sausage	x				x	x	x	x		x	x		
.142	Fresh Beef Sausage	x				x	x	x	x		x	x		
.143	Breakfast Sausage	x	x	x	x	x	x	x	x		x	x		
.144	Whole Hog Sausage	x						x	x					
.160	Smoked Pork Sausage	x				x	x	x	x		x	x		
.180(a)	Franks, Bologna, etc.	x				x	x	x	x		x	x		
.180(b)	Franks, Bologna, etc.	x	x	x	x	x	x	x	x		x	x		
.200	Braunschweiger	x	x	x	x	x	x	x	x		x	x		
.200	Liver Sausage	x	x	x	x	x	x	x	x		x	x		
.260	Luncheon Meat	x	x	x	x	x	x	x	x		x	x		
.261	Meat Loaf	x	x	x	x	x	x	x	x		x	x	x	x
.280	Scrapple	x	x	x	x	x	x	x	x		x	x	x	x
.281	Bockwurst	x	x	x	x	x	x	x	x		x	x		
.300	Chili Con Carne	x	x	x	x	x	x	x	x		x	x	x	x
.301	Chili Con Carne with Beans	x	x	x	x	x	x	x	x		x	x	x	x
.302	Hash	x	x	x	x	x	x	x	x		x	x	x	x
.303	Corned Beef Hash	x	x	x	x	x	x	x	x		x	x	x	x
.304	Meat Stews	x				x	x							
.305	Tamales	x	x	x	x	x	x	x	x		x	x	x	x
.306	Spaghetti and Meatballs, etc.	x	x	x	x	x	x	x	x		x	x	x	x
.307	Spaghetti Sauce with Meat	x	x	x	x	x	x	x	x		x	x	x	x
.310	Lima Beans with Ham, etc.	x				x								
.311	Chow Mein, Chopped Suey, etc.	x	x	x	x	x	x	x	x		x	x	x	x
.312	Pork with Barbecued Sauce Beef with Barbecued Sauce	x				x								
.313	Beef and Gravy, Gravy and Beef	x				x								
.500	Meat Pies	x				x								
.600(a)	Pizza	x	x	x	x	x	x	x	x		x	x	x	x
.760(a)	Deviled Ham, Tongue, etc.	x				x	x							
.761	Potted Meat, Deviled Meat	x	x	x	x	x	x	x	x		x	x	x	x
.762	Ham, Tongue Spreads, 50% of Product	x	x	x	x	x								
	50% Optional above	x	x	x	x	x	x	x	x		x	x	x	x

APPENDIX II
INTERIM REGULATION

PART 76—HOG CHOLERA AND OTHER COMMUNICABLE SWINE DISEASES

Release of Area Quarantined

Correction

In FR Doc. 76-11003 appearing at page 16145 in the FEDERAL REGISTER of Friday, April 16, 1976, the sixth line in the authority citation for § 76.2 should read as follows: "123-126, 134b, 134f); 37 FR 28464, 28477, 38".

CHAPTER III—ANIMAL AND PLANT HEALTH INSPECTION SERVICE (MEAT AND POULTRY PRODUCTS INSPECTION), DEPARTMENT OF AGRICULTURE

SUBCHAPTER A—MANDATORY MEAT INSPECTION

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

Definition of Meat Recovered by Mechanical Means and by Low Temperature Rendering Techniques

Purpose: The purpose of this document is to set forth in the Federal meat inspection regulations, on an interim basis, standards for product obtained from the mechanical deboning of meat tissues and for products recovered by low temperature rendering.

The Department is concurrently publishing a proposed rulemaking document which if adopted would redefine the term "meat" as used in the regulations. The proposal, in part, would provide for various categories of "meat," acceptable uses in formulated products for each category; appropriate amounts, if such restrictions are necessary; and parameters by which some of these categories, such as product recovered by mechanical separation from bone, and that recovered by low temperature rendering, could be judged acceptable. Additionally, information would be solicited as to the proper identification of these categories when used as ingredients of formulated meat products.

The proposed redefinition of "meat" appears to be especially appropriate at this time, since the world wide food shortage, especially of protein, makes it mandatory that all available food be retained for consumption. At the same time, the Department is well aware of its responsibilities to assure that meat and meat food products are wholesome, not adulterated, and properly marked, labeled, and packaged when distributed to consumers.

Some of the technologies developed to retain additional product from carcasses of livestock are new and have not been used sufficiently in this country to decide upon limits for protein, fat, and bone quantity, and protein quality that are appropriate and acceptable in various formulated products. Therefore, after careful consideration of the problem, analysis of the limited testing in this country, analysis of experiences of other countries which permit use of these systems, and the need for additional data, the Department has decided to publish the following interim rule as § 319.3 of the regulations. This rule will remain in effect pending the completion of the proposed rulemaking proceeding on the general revision of regulations concerning the definition of "meat," unless rescinded prior thereto. Therefore, Part 319 is amended by adding a new § 319.3 to read:

Section 319.3 is added as set forth below:

§ 319.3 Mechanically deboned and low temperature rendered meats.

(a) Mechanically deboned meat, mechanically deboned meat for processing, and mechanically deboned meat for rendering are those products resulting from the sanitary, mechanical separation of meat from bone by approved machinery and conforming to the parameters contained in Table 1, at end of this section.

(b) Low temperature rendered meat and low temperature rendered meat for processing are the products resulting from the sanitary low temperature (120° F. or less) rendering of meat tissue by approved machinery, and conforming to the parameters contained in Table 2, at end of this section.

(c) The maximum use levels of products defined in § 319.3 (a) and (b) are as follows:

(1) Mechanically deboned meat, low temperature rendered meat, or any combination thereof shall be limited to a maximum of 20 percent of the meat or meat and meat byproducts content of formulated products.

(2) Mechanically deboned meat for processing, low temperature rendered meat for processing, or any combination thereof shall be limited to 15 percent of the meat or meat and meat byproducts content of formulated products.

(3) Any combination of products specified in subparagraphs (c)(1) and (c)(2) shall be limited to 15 percent of the meat or meat and meat byproducts content of formulated products.

(4) Mechanically deboned meat for rendering as such may not be used in any formulated meat product. After rendering so that it meets the respective standard, it may be used as low temperature rendered meat or low temperature rendered meat for processing.

(d) Products defined in §§ 319.3(a) and 319.3(b) may be used in any formulated product except hamburger, ground beef, fabricated steaks and products traditionally prepared with larger pieces of meat such as "beef and gravy," "lamb stew," and "pork and dressing," and may be identified in the labeling by the species name, e.g., beef, pork, etc.

(e) In preparing product defined in §§ 319.3(a) and 319.3(b), the establishment operator shall:

(1) Apply for label approval listing equipment and processing procedures,

(2) Develop a quality assurance system to control product compliance, and

(3) Obtain approval of the quality assurance system from the Department[1] prior to starting operations.

(f) The Department will conduct sampling, analytical, and inspection procedures to confirm accuracy of establishment results and assure product compliance.

TABLE 1.—*Mechanically deboned products*

Product	Protein minimum (percent)	PER[2] minimum or	Essential[1][3] amino acids minimum (percent)	Fat maximum (percent)	Calcium maximum (percent)
Mechanically deboned meat	14	[4] 2.5	[3] 32	30	0.5
Mechanically deboned meat for processing	10	[4] 2.5	[3] 32	60	.75
Mechanically deboned meat for rendering[5]					

TABLE 2.—*Low temperature rendered products*

Product	Protein minimum (percent)	PER[2] minimum or	Essential[1][3] amino acids minimum (percent)	Fat maximum (percent)	Calcium maximum (percent)
Low temperature rendered meat	15	[4] 2.5	[3] 32	20	0.5
Low temperature rendered meat for processing	20	[4] 2.0	[3] 27	20	.5

[1] As a percent of total protein.

[2] Exclusive of tryptophane, but including phenylalanine, isoleucine, leucine, lysin, methionine, valine, and threonine.

[3] PER may be calculated from the following equations in lieu of PER determination or percent essential amino acids.

1. PER = 0.456 (Leucine) − 0.047 (Proline) − 0.084.
2. PER = 0.435 (Methionine) + 0.780 (Leucine) + 0.211 (Histidine) − 0.911 (Tyrosine) − 1.816. Amino acid values in these equations are expressed as percent of total protein

[4] Adjusted to 2.50 for standard casein.

[5] Fails to meet any of the requirements for mechanically deboned meat for processing.

The purpose of this amendment is to gather data in connection with the proposed redefinition of the term "meat" being published simultaneously herewith, and will provide invaluable input for decisionmaking on final rulemaking. Therefore, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that further notice or public rulemaking proceedings on these amendments are impractical and unnecessary, and that good cause is found for making this amendment effective in less than 30 days after publication in the FEDERAL REGISTER.

Effective: April 27, 1976.

Done at Washington, D.C., on: April 23, 1976.

F. J. MULHERN,
Administrator, Animal and Plant Health Inspection Service.

[FR Doc.76-12272 Filed 4-26-76;8:45 am]

[1] Such approval may be requested from the Systems Development and Sanitation Staff, Technical Services, Meat and Poultry Inspection Program, 14th and Independence Avenue SW., Washington, D.C. 20250.

APPENDIX III
TEMPORARY COURT INJUNCTION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

COMMUNITY NUTRITION INSTITUTE, et al.,	:	
	:	
Plaintiffs,	:	
	:	Civil Action
v.	:	
	:	No. 76-1585
EARL L. BUTZ, Secretary of Agriculture,	:	Filed
	:	Sept. 10, 1976
Defendant.	:	James F. Davey, Clerk

MEMORANDUM AND ORDER

This matter is now before the Court on plaintiffs' Motion For Preliminary Injunction, and defendant's opposition thereto. In this action plaintiffs, various consumer-oriented public interest groups, state officials, and a Member of Congress, challenge the action of the Secretary of Agriculture in promulgating, without notice, public participation, or thirty-day delayed effective date, a new regulation which for the first time gives the formal sanction of the Department to the use of Mechanically Deboned Meat (MDM) as a constituent element of certain food products under his regulatory supervision. The regulation, 9 CFR § 319.3, was published at 41 Federal Register 17535 on April 27, 1976, to be effective immediately.

Mechanically deboned meat is produced by pulverizing bones from which most meat has been removed by traditional hand means, then centrifuging the resultant mash through a fine sieve. The technology for producing MDM from red meat without undue bone fragments or metal slivers has only recently been developed. The machinery currently in use allows bone particles in MDM of a diameter of approximately .018 inches. The Department has been involved in the observation and supervision of such developing technology for about fifteen years, and in late 1974 felt that MDM technology had advanced to the point where it could produce acceptable red meat MDM for American consumption. Consequently, in November of 1974 it issued a bulletin to its inspectors, State officials, and meat producers specifying that MDM could thereafter be produced and sold in the United States under certain conditions and with certain specifications. Those specifications were subsequently revised, and on April 27th of this year the Department issued the instant regulation further modifying those specifications and defining the permissible uses of MDM. The regulation is issued as one of the "definitions and

standards of identity or composition" for meat products pursuant to 21 U.S.C. § 607(c), part of the Federal Meat Inspection Act. Plaintiffs challenge the regulation as defective under the Administrative Procedure Act and as in substantive conflict with the Federal Meat Inspection Act, as amended, 21 U.S.C. §§ 601 et seq. Plaintiffs' basic claim in this regard is that the regulation permits the sale of adulterated and misbranded meat, contrary to the provisions of the Act. The Court entered a temporary restraining order against the operation of the regulation on September 1, 1976. Oral argument on the motion for preliminary injunction was held on September 9, 1976.

The standards for the issuance of a preliminary injunction are generally those found in Virginia Petroleum Jobbers Assn. v. F.P.C., 259 F.2d 921 (C.A.D.C., 1958). However when federal statutes have been violated, it has long been the rule that a court need not inquire into the traditional requirements for equitable relief. See, United States v. City and County of San Francisco, 310 U.S. 16 (1940); Atchison, Topeka, and Santa Fe Railway Co. v. Callaway, 382 F. Supp. 610, 623 (D.D.C., 1974); Lathan v. Volpe, 455 F.2d 1111, 1116 (C.A. 9, 1971). In any event, the facts of this case do satisfy the traditional requisites for the issuance of a preliminary injunction.

I. SUCCESS ON THE MERITS

A. The Administrative Procedure Act Claims

The Secretary relies principally upon the "interpretative rule" exception to the requirements of 5 U.S.C. §§ 553 (b), (c), and (d), and secondarily on the "good cause" exception to those requirements, to excuse his failure to comply with the ordinary procedures of the APA. He argues that this regulation is merely an interpretative rule which states his opinion as to what does and does not constitute adulteration and misbranding, and has no force of law. These arguments are without merit. The Department has been deeply involved in the regulation of MDM for many years, and both it and the meat packing industry consider this regulation as an explicit limitation on the composition and uses of the product. When a regulatory agency exercises its statutory authority to set standards and prescribe conduct, as is the case here, it must do so in accordance with the substantive rulemaking provisions of the APA. This regulation is a "definition and standard of identity or composition", 21 U.S.C. § 607(c), and is civilly and criminally enforceable; indeed, the Department explicitly states that one of its purposes in promulgating the regulation is to have an enforceable limit on MDM content. In these circumstances, no serious contention can be made that the rule is within the exception to the rulemaking requirements of the APA as merely "interpretative". For like reasons, the Secretary's

reliance on Skidmore v. Swift & Co., 323 U.S. 134 (1944) is wholly misplaced; the relationship between the situation at issue there and the present case is at best remote.

The "good cause" exemption to the rulemaking requirements is also inapplicable to the circumstances of this case. The Secretary specifies as the good cause for ignoring those requirements the need to obtain information and data for use in connection with the proposed rulemaking proceedings, related to the production of MDM and other matters, initiated at the same time as the promulgation of this "interim" rule. However when a health-related standard such as this is involved, the good cause exemption may not be used to circumvent the legal requirements designed to protect the public by ensuring that interested persons will have the opportunity to bring to the agency's attention all relevant aspects of the proposed action and thereby enhance the quality of agency decisions. If the Department wanted information to use in its rulemaking process, it could have simply required the industry to supply that information as a condition precedent to the approval of MDM under the Federal Meat Inspection Act as safe. The law requires the Secretary to determine that meat is not adulterated or to condemn that meat; the fact that he may not have the data necessary to make a determination of safety means that he cannot rule that meat is not adulterated, not that he may suspend the rulemaking requirements of the APA and expose the public to uncertain hazards while he collects information necessary to make those decisions. Indeed, the Secretary states in the preamble to the interim rule that the technology has "not been used sufficiently in this country to decide upon limits for protein, fat, and bone quantity, and protein quality that are appropriate and acceptable in various formulated products." 41 Fed. Reg. 17535. Far from being good cause for circumventing the normal rulemaking requirements, this constitutes a compelling reason to utilize those procedures before subjecting the public to any possible hazard. Accordingly, the Court holds that the promulgation of this regulation was in violation of the Administrative Procedure Act, and that in this regard plaintiffs are likely to succeed on the merits of their contentions.

B. Adulteration

Plaintiffs contend that processed meat products containing MDM, which this regulation permits to be sold in the United States, should be considered adulterated within the meaning of the Federal Meat Inspection Act. Such products are "meat food products", 21 U.S.C. § 601(j). Under subsection (m) of that section, such a product is adulterated:

> (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance

is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

* * *

(8) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if any damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is;

* * *

The Secretary argues that MDM containing bone particles or products containing MDM cannot be adulterated because the bone is actually "meat" under the Department's 1938 definition of meat, found at 9 C.F.R. § 301.2(tt). That section provides:

Meat. The part of the muscle of any cattle, sheep, swine, or goats, which is skeletal or which is found in the tongue, in the diaphragm, in the heart, or in the esophagus, with or without the accompanying and overlying fat, and the portions of bone, skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing. * * *

It seems almost too obvious to have to state that the bones permitted in meat by this definition are the t-bones in t-bone steaks or the leg in leg-of-lamb and the like. Ground up bits of bone entering the meat in the mechanical deboning process, or entering a processed meat with the addition of MDM, is clearly and totally outside the contemplation of this definition.

Section 601(m)(1) and (8) require the determination of whether a substance is an "added" substance as part of the determination of adulteration. Because bone particles are not part of "meat", they must be regarded as having been added to MDM during the mechanical process; obviously, bits of crushed bone do not "normally accompany the muscle tissue" after it is dressed by hand. Likewise, bone particles must be regarded as having been added to any final processed product to which MDM itself has been added. Section 601(m)(8), dealing with so-called economic adulteration, includes any such product where the added substance reduces the quality of the substance. The Court does not now have sufficient information to determine whether the use of MDM in

processed or rendered products reduces their quality; the criteria for this determination appear to be nutritional and aesthetic. The Secretary claims to have determined that these criteria are satisfied at the levels specified by the regulation.

As to the more health-related aspect of adulteration [601(m)(1)], however, it is likely that the Secretary's approval of the use of MDM in this regulation will be found clearly erroneous. In the case of an added substance, the Secretary is required by the act to condemn meat containing such a substance if the substance "may render it injurious to health" (emphasis added). In order for the Secretary to approve the use of MDM as he has done in this regulation, therefore, he is required by law to have made a determination that there is no substantial possibility that the presence of bone particles in a concentration of .45% in processed products containing MDM could harm the health of those ingesting the products. It is not at all clear that the Secretary has made such determination with the required thoroughness. In his preamble accompanying the proposed rulemaking issued at the same time as the interim regulation, he states:

> It is the Department's present position that the bone, if present in such a particle size or in such an amount as to be readily apparent to the taste or touch, would indeed be identifiable as bone and would be a reason for considering the product to be adulterated. However, modern equipment can minimize the particle size and level of bone to an extent that it cannot be detected by sensation in the mouth.

41 Fed. Reg. 17561. While this is a relevant consideration in terms of economic adulteration, it in no way satisfies the requirements under subsection (m)(1). The Secretary argues that he has also studied the nutritional aspects of MDM use, particularly in terms of its calcium content (bone is approximately 25% calcium) and the calcium requirements of the American diet. While nutrition is one criterion of the section 601(m)(1) health effects, and while the Court cannot say the Secretary's treatment of that issue is inadequate, consideration of nutritional problems alone is an insufficient basis for the health determination required. The Secretary argues that he has considered all health questions involved and has concluded that no health threats exist; he has submitted copies of some of the relevant literature to underscore this claim. A perusal of that literature, however, establishes that the Secretary has failed to consider adequately the health effects of MDM in at least three significant ways: first, the possible gastroenterological side effects which may result from frequent ingestion of bone particles; second, the possibly unduly high levels of strontium-90 which may be contained in bone particles in red meat MDM; third, the possible long-term

effects of the fat content present in MDM on the cardio-vascular systems of those Americans for whom processed meat products constitute a significant portion of their diets. Accordingly, until the Secretary has adequately assessed these questions, MDM must be considered as a substance which may injure health, and therefore adulterated and an adulterant.

C. Misbranding

A product is "misbranded" under § 601(n)(1) "if its labeling is false or misleading in any particular". While this issue has not been as fully argued by the parties, it does appear to the Court that the interim regulation permits misbranding of a product labeled, for example, "all beef franks," since the calcium content of such a product would be higher than that of a comparable product without MDM. Since the public expects the usual product, it would be misled by the labeling permitted by the regulation. This could prove especially harmful to persons on calcium-restricted diets, who would be misled into thinking that the product contained no more than the usual amount of calcium. Moreover, since no standards of identity or composition for meat food products, where such standards exist, have been amended by the regulation, any such product containing MDM pursuant to the interim regulation would be misbranded under subsection (n)(7), as being at variance with such standards.

II. OTHER INJUNCTIVE RELIEF CONSIDERATIONS

A. The Public Interest

The paramount public interest to be vindicated here is the protection of the consuming public against possible health hazards posed by the use of MDM in meat products. The Secretary makes the argument--apparently seriously--that if this regulation is enjoined there will be no constraints on the inclusion of MDM in meat products by the meat packing industry. However, the Secretary is required by § 606 of the Act to prevent the sale of any adulterated meat food products. In light of the fact that he has not made the studies and assessments necessary to say that MDM does not adulterate such products, the Court can only assume that he will faithfully execute his duty under the law to prevent the distribution and sale of such products. No argument that he is powerless to do so can be made in good faith.

B. Harm To The Defendants

No significant harm will be visited upon the defendant by the suspension of the interim regulation. If he wants data on the mechanical deboning

process and on the resulting product, he may require such information of the meat packers or may conduct such tests as are necessary himself. He may also conduct proceedings in conformity with the APA as may be appropriate. As to the harm to the meat packing industry, Congress has unequivocally determined that public health is to take precedence over commercial interests in this matter, and anything of which they are being deprived today is something to which they have no vested right, but are permitted to do only when certain regulatory prerequisites have been met. This process may of course be hastened by the cooperation of the industry in the development of the data necessary for that regulatory approval to be properly consummated.

C. Irreparable Injury

The irreparable injury in this case is clear: the consumers represented by plaintiffs will be subject to unknown health hazards in the absence of this injunction. As we are becoming increasingly aware, ingestion of substances of whose effects we are uncertain now can have profound ramifications for our health much later. No possible way exists to compensate in the future for health problems triggered in the present, and this problem is especially significant to those low-income persons who are proportionally the greatest consumers of the products in which MDM is contained. Finally, it is well established that the harm suffered by those who would otherwise participate in agency rulemaking under the APA is to be considered irreparable when the agency fails to afford them their rights to such participation. Accordingly, it is by the Court this 10th day of September, 1976,

ORDERED, that plaintiffs' Motion for Preliminary Injunction be, and hereby is, granted; and

FURTHER ORDERED, that defendent Earl L. Butz, Secretary of Agriculture, his officers, servants, agents, employees, attorneys, and persons in active concert with him, are hereby enjoined from giving further effect to Section 319.3 of Title 9, Code of Federal Regulations, with respect to Mechanically Deboned Meat.

/s/ William B. Bryant
JUDGE

APPENDIX IV
ANALYTICAL DATA

The Food Safety and Quality Service wishes to extend its special appreciation to the Health and Safety Laboratory, Energy Research and Development Administration, New York, New York, the Winchester Engineering and Analytical Center, Food and Drug Administration, Winchester, Massachusetts, and Technological Resources Incorporated, Camden, New Jersey, for the cooperation and invaluable assistance provided in this study.

A. SELECTION OF SAMPLES OF MECHANICALLY DEBONED BEEF AND PORK

In none of the cases described below were the samples selected at random. Every effort was made to obtain a geographical distribution. But, since a truly random sample was precluded by forces that could not be controlled, the judgment of our staffs was used in obtaining the most representative samples obtainable. Therefore, inference from the analyses should be considered advisory and not scientifically conclusive. The data obtained were the best available. Unless we permit MDM to be commercially produced or devise an elaborate expensive laboratory experiment, the data cannot be improved upon.

Phase I

This was designed as a pilot study to determine changes in trace element levels between muscle tissue and MDM. The study was interrupted because production of MDM was halted. Data were collected from a total of eight lots from two geographical areas.

Samples for this phase were collected by USDA inspectors assigned to these establishments. The inspectors had been instructed to obtain samples of hand-deboned meat from the same lots of animals that supplied the bones used in mechanical deboning. Samples of hand-deboned meat which they obtained were very lean, as indicated by contents of protein and chemical fat. Because trimmings used in production of formulated

meat products vary from very lean to very fat, the samples of hand-deboned meat in this study would not necessarily be representative of meat trimmings which might be replaced by MDM. Thus, comparisons of data from Phase I of this study for hand-deboned meat and MDM might suggest differences in composition between muscle and MDM, but should not be interpreted as indicating differences that could be expected in composition of final products containing or not containing MDM.

Phase II

When the order to cease production of MDM was given, each region was requested to have each plant that was producing MDM at that time provide a sample of their product to the Meat and Poultry Inspection Program in order to obtain data on trace elements and other components. This sampling program provided samples of MDM which were judged to be reasonably representative of production from those plants. However, these samples could not be considered representative of nationwide production of MDM unless resulting data were weighted according to the proportion of total U.S. production coming from each of the plants.

In this phase of the study, 14 samples of mechanically deboned beef and 10 of mechanically deboned pork were collected.

Phase III

This phase was designed to study the PER OF MDM at three levels. Samples were collected from plants with anticipated low, medium, and

high PER levels. Anticipated PER's were calculated from data for amino acid content of lots of mechanically deboned beef which had been previously produced. These samples were also analyzed for trace elements, but because of the selection procedure used the data were not considered sufficiently representative to be used by the Panel in its evaluation. Trace element and proximate data are reported for comparison with values summarized from Phases II and IV. The two sets of data are in good agreement; thus, support is given to the conclusion that the summarized data from Phases II and IV are representative. A total of 30 samples from 8 establishments was collected.

Phase IV

Similar to Phase II in selection of samples, the samples were originally collected to study bacterial levels in MDM and were later analyzed for trace elements. These samples, like the samples in Phase II, were considered to be reasonably representative of production from the establishments. A total of 16 samples of mechanically deboned beef and 13 samples of mechanically deboned pork were available for analysis from this phase of sampling.

Particle Size

In addition to the available literature on the particle size and shape of the bone particles present in MDM, four samples of MDM (one from each of the four commercially available deboners) were evaluated.

B. SUMMARY OF RESULTS

The original laboratory compilations of data from which the summaries are derived are available upon request.

Data for the proximate components protein, moisture, fat, and ash and seven minerals in Phase I samples of mechanically deboned beef are summarized in Table IV-B-1. Corresponding data for Phase I samples of hand-deboned beef and differences between mechanically deboned and hand-deboned beef are also given in Table IV-B-1. As was pointed out in A of this Appendix these data show differences between MDM and muscle, but cannot be used to estimate increments in content of minerals if MDM were to replace meat trimmings in formulated products.

Data for Phase II samples are summarized in Table IV-B-2. Data are included for proximate components, seven minerals, strontium-90, total lipids and cholesterol content. As the table shows, there was not enough sample to make all determinations on all samples.

Table IV-B-3 gives a summary of the results of the amino acid and the PER determinations for the Phase III samples. Results of the proximate and trace element analyses for Phase III samples are shown in Table IV-B-4.

Data for mineral elements in Phase IV samples as well as the lipid and cholesterol content are given in Table IV-B-5. There was not

enough material to permit analyses for proximate components to be made on these samples.

The results of the data gathered on the chlorinated hydrocarbon content of MDM are summarized in Table IV-B-6. Most of these data were accumulated from Phase IV samples.

Table IV-B-7 contains a summary of data from Phases II and IV combined. These data were used in the consumption study and by the Select Panel in making its evaluations.

Table IV-B-8 summarizes the data generated on the bone particle size evaluation.

Table IV-B-1--Summary of Phase I Data--Composition of Mechanically Deboned Beef (MDB) and Hand Deboned[1] (HDB) in Two Geographical Locations

	Protein %	Moisture %	Fat %	Ash %	Lead[2] mcg/gm	Zinc mcg/gm	Calcium %	Fluoride mcg/gm	Iron mcg/gm	Nickel mcg/gm	Phosphorus %
Mississippi (MDB)											
Average	14.3	58.1	25.4	1.9	.14	36.7	.46	18.3	53.0	-	.30
Low	13.9	55.4	19.6	1.8	.09	33.8	.41	14.5	45.3	-	.24
High	15.1	62.4	28.6	2.0	.19	39.3	.50	24.5	57.2	-	.35
Mississippi (HDB)											
Average	20.3	72.3	6.7	1.0	.06	44.7	.01	.50	30.4	-	.20
Low	19.2	69.7	4.5	1.0	<.05	39.7	.01	.30	23.7	-	.16
High	21.6	74.0	9.2	1.1	.12	50.0	.01	.67	36.3	-	.24
Difference (MDB-HDB)											
Average	- 6.0	-14.2	18.7	.9	.08	- 8.0	.45	17.8	22.6	-	.10
Michigan (MDB)											
Average	15.1	58.4	24.6	1.8	.08	33.5	.39	11.4	81.7	.27	.30
Low	14.1	56.8	21.0	1.4	.07	26.4	.24	7.6	68.5	.15	.29
High	15.8	60.5	26.8	2.0	.09	40.7	.50	14.4	92.8	.36	.34
Michigan (HDB)											
Average	19.5	67.8	11.9	1.0	.05	64.8	.03	1.46	30.7	.21	.17
Low	18.3	61.8	8.4	1.0	<.05	49.9	.01	.88	23.3	.11	.15
High	20.7	70.2	18.2	1.1	.07	80.6	.03	1.90	41.1	.58	.18
Difference (MDB-HDB)											
Average	- 4.4	- 9.4	12.7	.8	.03	-31.3	.36	9.94	51.0	.06	.13

1 Cadmium not detected; minimum detection limit is .01 mcg/gm.
2 Minimum detection limit for lead is 0.05 mcg/gm. Less than .05 mcg/gm assumed to be .05 mcg/gm for calculation.

Table IV-B-2--Summary of Phase II Data--Composition of Mechanically Deboned Beef (MDB) and Mechanically Deboned Pork (MDP)[1]

	Protein %	Moisture %	Fat %	Ash %	Lead[2] mcg/gm	Zinc mcg/gm	Calcium %	Fluoride mcg/gm	Strontium-90 pC/gm	Nickel mcg/gm	Phosphorus %	Selenium[2] mcg/gm	Lipids %	Cholesterol mcg/gm
Beef														
Avg.	15.4 (n=4)	56.4 (n=4)	26.3 (n=4)	2.1 (n=4)	.11 (n=2)	32.3 (n=14)	.58 (n=4)	20.65 (n=4)	.097 (n=11)	.33 (n=2)	.34 (n=2)	<.05 (n=13)	28.42 (n=2)	990 (n=2)
Low	13.4	46.9	16.7	1.5	.07	20.7	.31	14.8	.044	.32	.25	<.05	19.24	875
High	17.1	63.2	38.6	2.6	.15	46.3	.89	27.2	.208	.33	.42	.07	37.59	1105
Pork														
Avg.	12.8 (n=9)	50.6 (n=9)	34.0 (n=9)	1.9 (n=9)	.07 (n=7)	23.5 (n=10)	.45 (n=10)	11.7 (n=9)	.029 (n=1)	.38 (n=2)	.32 (n=9)	.07 (n=10)	27.94 (n=2)	665.5 (n=2)
Low	11.1	45.4	28.9	1.1	<.05	18.7	.18	4.6		.30	.20	<.05	22.18	516
High	14.5	56.2	38.5	3.7	.15	26.7	.87	21.8		.45	.49	.10	33.70	815

1 Cadmium not detected; minimum detection limit is .01 mcg/gm.
2 Minimum detection limit for lead and selenium is 0.05 mcg/gm. Less than .05 mcg/gm assumed to be .05 mcg/gm for calculation.

Table IV-B-3--Summary of Phase III Data--Composition of Mechanically Deboned Beef[1]

	Protein	Moisture	Fat	Ash	Lead[2]	Zinc	Calcium	Fluoride	Iron	Nickel	Copper	Cobalt	Phosphorus	Strontium-90	Selenium[2]
	%	%	%	%	mcg/gm	mcg/gm	%	mcg/gm	mcg/gm	mcg/gm	mcg/gm	mcg/gm	%	pC/gm	mcg/gm
Avg.	13.2	49.1	35.3	2.4	.09	28.0	.70	17.8	43.4	.30	.45	.27	.39	50.3	.08
Low	9.9	37.5	15.4	1.6	<.05	17.3	.35	8.0	22.0	.19	.23	.16	.27	22.0	<.05
High	16.6	65.3	50.5	5.0	.22	43.3	1.74	34.4	69.3	.49	.70	.45	.79	86.0	.17
Std. Dev.	1.9	9.0	10.4	.6	.04	6.7	.27	6.9	14.2	.06	.13	.06	.10	23.2	.04

1 Cadmium not detected; minimum detection limit is .01 mcg/gm.
2 Minimum detection limit for lead and selenium is .05 mcg/gm. Less than .05 mcg/gm assumed to be .05 mcg/gm for calculation.

Table IV-B-4 Summary of Phase III Study
Protein Efficiency Ratio and Amino Acid Content

Average of Amino Acids as Percent of MDM

Processor	No. of Samples	TYR	PHE	LYS	HIS	ARG	ASP	GLU	HYPRO	THR	SER	PRO	ALA	GLY	VAL
A	8	.24	.45	.80	.29	.82	.91	1.47	.41	.33	.39	.68	.70	.95	.61
B	3	.39	.63	1.23	.49	1.17	1.31	2.17	.40	.48	.56	.81	.98	1.10	.95
C	4	.34	.61	1.09	.39	1.03	1.21	1.97	.50	.45	.53	.90	.97	1.12	.85
D	3	.36	.56	.99	.42	.99	1.14	1.86	.43	.45	.51	.71	.87	1.00	.77
E	3	.45	.66	1.29	.53	1.24	1.38	2.31	.36	.50	.60	.87	1.01	1.05	.93
F	3	.29	.56	.91	.30	.87	1.04	1.60	.46	.37	.47	.93	.89	1.14	.78
G	3	.44	.61	1.16	.49	1.15	1.37	2.18	.38	.45	.55	.88	.93	1.07	.93
H	3	.31	.53	.91	.35	.99	1.08	1.75	.78	.37	.48	.79	.86	1.18	.82
Grand Average	30	.33	.56	1.01	.39	1.00	1.14	1.84	.45	.41	.49	.79	.87	1.06	.79

Table IV-B-4 (Continued)

Processor	No. of Samples	Average Amino Acids					Proximate		Average PER			
		CYS	MET	ILU	LEU	% ESSENTIAL AMINO ACIDS	% PROT	% FAT	RAT GROWTH	EQUATION-1[2]	EQUATION-2[2]	EQUATION-3[2]
A	8	.14	.34	.39	.79	35.2	10.6	47.7	2.51	2.44	2.71	3.90
B	3	.24	.46	.65	1.26	39.4	14.4	31.8	2.61	3.05	3.22	4.57
C	4	.23	.49	.53	1.13	34.6	14.9	30.1	2.57	2.50	2.74	3.94
D	3	.25	.35	.50	1.06	37.4	12.5	23.3	2.66	2.92	3.08	4.02
E	3	.20	.26	.67	1.30	35.9	15.6	21.4	2.89	2.85	3.01	3.38
F	3	.22	.44	.47	1.01	36.3	12.5	41.9	2.52	2.64	2.95	4.30
G	3	.21	.27	.59	1.19	37.0	14.1	30.8	2.97	2.90	3.04	3.40
H	3	.19	.30	.46	.97	35.1	12.4	43.9	2.43	2.59	2.82	3.57
Grand Average	30	.20	.36	.51	1.04	36.1	13.0	36.1	2.62	2.68	2.90	3.89

1 TYR (Tyrosine), PHE (Phenylalanine), LYS (Lysine), HIS (Histidine), ARG (Arginine), ASP (Aspartic Acid), GLU (Glutamic Acid), HYPRO (Hydroxyproline), THR (Threonine), SER (Serine), PRO (Proline), ALA (Alanine), GLY (Glycine), VAL (Valine), CYS (Cystine), MET (Methionine), ILU (Isoleucine), and LEU (Leucine).

2 Calculated using equations described by Alsmeyer, R. A., Cunningham, A. E., and Happich, M. L. (1974). Equations Predict PER from Amino Acid Analysis--Food Technology 28(7) 34-36, 38-40.

Table IV-B-5--Summary of Phase IV Data--Composition of Mechanically Deboned Beef and Mechanically Deboned Pork[1]

	Lead[2] mcg/gm	Zinc mcg/gm	Calcium %	Fluoride mcg/gm	Iron mcg/gm	Nickel mcg/gm	Selenium[2] mcg/gm	Copper mcg/gm	Cobalt mcg/gm	Lipids %	Cholesterol mcg/gm
BEEF											
Average	.09	35.9	.60	18.1	40.9	.33	.08	.54	.29	30.7	874.9
Low	.06	22.5	.24	7.8	20.4	.20	<.05	.26	.18	22.2	284.4
High	.14	59.4	1.10	32.5	56.3	.58	.14	.81	.56	50.1	2018.5
Std. Dev.	.03	10.9	.24	7.2	9.7	.08	.03	.16	.10	9.0	437.9
PORK											
Average	.06	22.9	.38	10.4	19.9	.32	.14	.70	.23	30.2	780.1
Low	<.05	13.0	.12	2.3	13.0	.18	<.05	.57	.13	20.0	313.6
High	.07	27.9	.77	25.0	26.9	.56	.28	.92	.50	44.0	1117.7
Std. Dev.	.01	3.8	.21	5.9	3.9	.12	.08	.11	.10	6.4	281.3

1 Cadmium not detected; minimum detection limit is .01 mcg/gm.
2 Minimum detection limit for lead and selenium is 0.05 mcg/gm. Less than .05 mcg/gm assumed to be .05 mcg/gm for calculations.

Table IV-B-6--Summary of Data on Chlorinated Hydrocarbons from Phase II (4 samples) and Phase IV (29 samples)

	Number of Samples in Ranges Indicated										Highest level found	
	Not detectable		.01-.05 mcg/gm		.06-.1 mcg/gm		.1-.3 mcg/gm		.3-1 mcg/gm			
PESTICIDE	Beef	Pork	Beef	Pork	Beef	Pork	Beef	Pork	Beef	Pork	Beef	Pork
											mcg/gm	
BHC	12	11	8	2							.02	.02
DDT	2	6	7	4	3	1	5	4	1		.69	.15
Dieldrin	14	12	4	3							.03	.02
HCB	13	11	5	2				2			.02	.34
Heptachlor	13	11	5	4							.05	.03
Lindane	13	11	5	4							.04	.02

Table IV-B-7--Summary of Phase II and Phase IV Data Combined

ELEMENT	Sample Size		Average		Std Dev		Range Lower		Range Upper		90th Percentile	
	Beef	Pork	Beef	Pork	Beef	Pork	Beef	Pork	Beef	Pork	Beef	Pork
Zinc (mcg/gm)	30	23	34.2	23.2	9.56	3.38	20.7	13.0	59.4	27.9	46.8	27.6
Iron (mcg/gm)	16	13	40.9	19.9	9.74	3.93	20.4	13.0	56.3	26.9	53.9	25.2
Fluoride (mcg/gm)	20	22	18.6	11.0	6.88	5.58	7.8	2.3	32.5	25.0	27.8	18.3
Calcium (%)	30	23	.59	.41	.21	.21	.24	.12	1.10	.87	.86	.69
Lead[2] (mcg/gm)	14	16	.09	.06	.03	.03	.06	<.05	.15	.15	.13	.10
Nickel (mcg/gm)	18	15	.33	.33	.08	.12	.20	.18	.58	.56	.44	.49
Copper (mcg/gm)	16	13	.54	.70	.16	.11	.26	.57	.81	.92	.75	.85
Cobalt (mcg/gm)	16	13	.29	.23	.10	.10	.18	.13	.56	.50	.42	.37
Strontium-90[3] (pC/gm)	19	1	.077	.03	.048		.022		.208		.142	
Selenium[2] (mcg/gm)	29	23	.07	.11	.03	.07	<.05	<.05	.14	.28	.10	.20
Total Lipids (%)	17	15	30.5	29.9	9.08	6.36	19.2	20	50.1	44	42	38.4
Cholesterol (mcg/gm)	18	15	888	765	414.9	269.5	284	314	2019	1117	1440	1126

1 Cadmium not detected; minimum detection limit is .01 mcg/gm.
2 Minimum detection limit for lead and selenium is 0.05 mcg/gm. Less than 0.05 mcg/gm assumed to be 0.05 mcg/gm for calculations.
3 Summary includes data from Phase II, Phase III, and Phase IV.

Table IV-B-8--Summary of Bone Particle Size Determination

SAMPLE	Largest Size Found (Microns)[1] ERDA	USDA Method 1	USDA Method 2	Percent of Particles 450 Microns or less[1,2] USDA Method 1	USDA Method 2	Particles per mg Bone	Particles per gm MDM
1	420	500	600	99	99	15,729	203,691
2	300	350	400	100	100	23,344	429,530
3	840	650	650	99	98	6,280	53,694
4	660	500	550	99	99	7,790	105,555
Bone Meal		150		100			

1 Samples were analyzed microscopically. The ERDA laboratory measured bone particles on glass slides. The USDA determinations were made on glass slides of stained MDM tissue (Method 1) and a glycerine suspension of bone particles recovered after digestion (Method 2).

2 450 microns approximates the sieve size in mechanical deboners.

C. METHODS OF ANALYSIS

Table IV-C-1 summarizes the laboratories and the methods of analysis used. Details of the methods are available upon request.

As shown in the table, methods used for a number of substances were cross-checked by different laboratories. Data from these cross-checks were for the most part in excellent agreement with data from the principal laboratory. However, minor analytical problems were identified in the data for cadmium, lead, and fluoride.

Data for cadmium and lead in mechanically deboned and hand-deboned meat as determined by the Meat and Poultry Inspection Program laboratories using both unpublished and modified atomic absorption spectrophotometry (AAS) methods, by the Food and Drug Administration Laboratory using an anodic stripping voltammetry (ASV) method, and by the Wisconsin Alumni Research Foundation (WARF) using a modified AAS method are given in Table IV-C-2. As this table shows, values obtained by the unpublished AAS method were substantially higher than the other methods for cadmium and lead in both hand-deboned and mechanically deboned meat. The problem was found to be interferences from light scattering which caused false high readings in the AAS procedure. Subsequently, through modification of ashing procedures and by use of background correction during the AAS analyses, USDA chemists were able to obtain results comparable to those obtained by FDA using the ASV procedure, and by WARF. Details of these procedures are available upon request. The variability among

laboratories emphasizes the difficulty in analyzing elements present at levels so close to the levels of detectability. The lowest reliable limits of detection using the modified AAS technique are 0.01 ppm for cadmium and 0.05 ppm for lead.

All data for cadmium and lead used in consumption studies and reported in Tables IV-B-1 through 7 were obtained by the modified AAS technique. These data are judged to be accurate by both USDA and FDA chemists.

Comparisons of data for fluoride obtained by USDA using routine methods for meat with data obtained by Veterans Administration (VA) chemists using the diffusion method of Singer and Armstrong indicated that the USDA values were low. Subsequent investigation disclosed that the fluoride electrode, though new, was faulty, and it was replaced. Using the new electrode, USDA repeated the analyses. The new data, which are reported with the VA values in Table IV-C-3, were not significantly different.

As a further check on the fluoride methodology, some of the same samples which had been analyzed by both VA and USDA chemists were analyzed by FDA chemists, using both diffusion and fluoride electrode procedures. In addition, samples of hand-deboned beef were also analyzed by both methods in the FDA laboratories. Results of these analyses are also given in Table IV-C-3.

The FDA results for MDM using the USDA fluoride electrode method were 14 to 45 percent lower than the USDA results. FDA's and VA's results by

diffusion were on the average in good agreement with USDA results by fluoride electrode although individual samples showed divergent results in some instances. Mean recoveries, which were based on samples fortified with the equivalent of 10 ppm fluoride, were 100 $\pm$ 10 percent for both methods. However, individual recoveries were considerably more variable for the diffusion method than for the USDA method. Because no standard reference material similar to the meat samples exists for fluoride, the accuracy of the methods was based largely on the recoveries of these aqueous fluoride spikes to the samples. In most digestion procedures (such as wet digestion) a quantitative recovery of the spike, i. e., essentially 100%, is a good indicator that a quantitative recovery is also being obtained from the sample. With the USDA fluoride method, however, complete destruction of the sample matrix does not occur and as a result it is possible that some fluoride may be left in the sample matrix even though there is a quantitative recovery of the aqueous spike. The good agreement noted in results found by USDA using the fluoride electrode as compared with the diffusion method indicate that it is possible to measure the total fluoride by the electrode method. The value of checking a procedure by use of an alternate method is indicated by the relatively poor agreement between FDA and USDA values using the fluoride electrode.

Based on the above evaluation, FDA chemists recommended that USDA values for fluoride be used in evaluating health and safety effects of the use of MDM in processed meats. In view of the close checks with VA data and the recommendation from FDA, USDA chemists concluded that the fluoride

electrode method was adequate in accuracy and precision and determinations on hand-deboned and mechanically deboned meats were completed.

Table IV-C-1--Summary of the Methods of Analysis

TEST	Primary Laboratory	Method Reference	Verification Laboratory	Method Reference
PROTEIN	Special Projects Lab. FSQS, USDA, Wash., D.C.	Official Methods of Analysis (1975), AOAC Procedure 24.024, 12th Ed. Wash., D.C.	Technological Resources, Inc., Camden, NJ	(Same as primary lab)
FAT	"	AOAC Procedure 24.005 12th Ed. (1975)	"	"
ASH	"	AOAC Procedure 31.013 12th Ed. (1975)	"	"
MOISTURE	"	AOAC Procedure 24.003 12th Ed. (1975)	"	"
BONE SIZING	Pathology Lab., FSQS, USDA, Wash., D.C.	Unpublished Microscopic Methods	None	
	Health & Safety Lab. ERDA, N.Y., NY	Unpublished Microscopic Method		
PERCENTAGE BONE	Special Projects Lab. FSQS, USDA, Wash., D.C.	Unpublished Method	None	
CADMIUM	Chemistry Lab., FSQS, USDA, Omaha, NE	Modified AOAC Procedure 25.065, 12th Ed. (1975)	Analytical Chemistry & Physics Branch, FDA, Wash.,D.C.	Jones, J.W., Gajan, R.J., Boyer, K.W., and Fiorino, J.A., (1977) Dry Ash - Voltammetric Determination of Cadmium, Copper, Lead, and Zinc in Foods, JAOAC, 60(4), 826-832.
CALCIUM	Methods Development Lab., FSQS, USDA, Wash., D.C.	Modified AOAC Procedure 2.096, 12th Ed. (1975)	Special Projects Lab., FSQS, USDA, Wash., D.C.	Unpublished EDTA Titration Method
			Analytical Chemistry & Physics Branch, FDA, Wash., D.C.	Unpublished Dry Ash - Induction Coupled Plasma Method
			Health & Safety Laboratory, ERDA, N.Y., NY	Modified AOAC Procedure 2.096, 12th Ed. (1975)

Table IV-C-1 (Continued)

TEST	Primary Laboratory	Method Reference	Verification Laboratory	Method Reference
FLUORIDE	Special Projects Lab., FSQS, USDA, Wash., D.C.	Unpublished Specific Ion Electrode Method	Veterans Administration Hospital, Hines, IL	Singer, L., and Armstrong, W. D. (1959) Determination of Fluoride in Blood Serum, Analyt. Chem. 31. (1), 105-109.
LEAD	Chemistry Lab., FSQS, USDA, Omaha, NE	Modified AOAC Procedure 25.065, 12th Ed. (1975)	Analytical Chemistry & Physics Branch, FDA, Wash., D.C.	Jones, J.W., Gajan, R.J., Boyer, K.W., and Fiorino, J.A. (1977) Dry Ash - Voltammetric Determination of Cadmium, Copper, Lead, and Zinc in Foods, JAOAC, 60(4), 826-832.
SELENIUM	Methods Development Lab., FSQS, USDA, Wash., D.C.	Andreasen, C. A., and Vasco, G. A. Determination of Selenium in Animal Tissues (Unpublished).	None	
STRONTIUM-90	Health & Safety Lab., ERDA, N.Y., NY Winchester Engineering & Analytical Center, FDA, Winchester, MA	Health & Safety Lab Manual for Standard Procedures #300. "	None	
COBALT	Methods Development Lab., FSQS, USDA, Wash., D.C.	Andreasen, C. A., and Vasco, G. A., Determination of Cadmium, Cobalt, Copper, Iron, Manganese, Nickel, and Zinc in Animal Tissue by Atomic Absorption Spectroscopy (Unpublished)	None	
COPPER	"	Modified AOAC Procedure 2.096, 12th Ed. (1975)	None	

Table IV-C-1 (Continued)

TEST	Primary Laboratory	Method Reference	Verification Laboratory	Method Reference
IRON	Special Projects Lab, FSQS, USDA, Wash., D.C.	AOAC Procedure 14.011, 12th Ed. (1975)	Methods Development Lab, FSQS, USDA, Wash., D.C.	Andreasen, C. A., and Vasco, G. A. Determination of Cadmium, Cobalt, Copper, Iron, Manganese, Nickel, and Zinc on Animal Tissue by Atomic Absorption Spectroscopy (Unpublished).
		Modified AOAC Procedure 2.096, 12th Ed. (1975)	Methods Development Lab, FSQS, USDA, Wash., D.C.	
NICKEL	Methods Development Lab, FSQS, USDA, Wash., D.C.	Modified AOAC Procedure 25.041, 12th Ed. (1975)	None	Analytical Chemistry & Physics Branch, FDA, Wash., D.C. Unpublished Dry Ash - Induction Coupled Plasma Method
ZINC	Methods Development Lab, FSQS, USDA, Wash., D.C.	Modified AOAC Procedure 2.096, 12th Ed. (1975)	Analytical Chemistry & Physics Branch, FDA, Wash., D.C.	Unpublished Dry Ash - Induction Coupled Plasma Method
CHLORINATED HYDROCARBONS	Special Projects Lab., FSQS, USDA, Wash., D.C.	Unpublished Gas-Liquid Chromatographic Method	None	
	Eastern Multidisciplinary Lab., FSQS, USDA, Athens, GA	"		
	Western Multidisciplinary Lab., FSQS, USDA, San Francisco, CA	"		
TOTAL LIPIDS	Chemistry Lab., FSQS, USDA, Kansas City, MO	FDA Interim Methodology Instructions #2 for Fat, Fatty Acids, & Cholesterol	None	

Table IV-C-1 (Continued)

TEST	Primary Laboratory	Method Reference	Verification Laboratory	Method Reference
CHOLESTEROL	Chemistry Lab., FSQS, USDA, Kansas City, MO	FDA Interim Methodology Instructions #2 for Fat, Fatty Acids, and Cholesterol	Technological Resources, Inc., Camden, NJ	(Same as primary lab)
PER	Technological Resources Inc., Camden, NJ	AOAC Procedure 43.183, 12th Ed. (1975)	None	
AMINO ACID PROFILE	Technological Resources Inc., Camden, NJ	Modified Moore and Stein Column Chromatography Procedure	None	
MANGANESE	Methods Development Lab., FSQS, USDA, Wash., D.C.	Modified AOAC Procedure 2.096, 12th Ed. (1975)	None	
PHOSPHORUS	Special Projects Lab., FSQS, USDA, Wash., D.C.	AOAC Procedure 24.012, 12th Ed. (1975)	None	

Table IV-C-2 Comparison of Methods for Determining Cadmium and Lead in Hand-Deboned Meat and Mechanically Deboned Meat

Sample Description	Cadmium			Lead							
	USDA		FDA	USDA						WARF[4]	FDA
	Unpublished AAS[1]	Modified AAS[2]	ASV[3]	Unpublished AAS[1]			(Modified) AAS[2]			Modified AAS[2]	ASV[3]
				Lab 1	Lab 2	Lab 3	Lab 1	Lab 2	Lab 3		
	ppm	ppm	ppm	ppm	ppm	ppm	ppm	ppm	ppm	ppm	ppm
Mechanically Deboned Meat											
A	.05	<.01	.002	.80	.68	.62	--	.07	.15	.1	.13
B	.05	<.01	.002,.003	.71	.42	.61	--	<.05	<.05	.05	.09,.09
C	.04	<.01	.002	.83	.22	.56	--	<.05	.10	.05	.11
D	.05	<.01	.003,.003	.77	.29	.69	--	.12	.21	.15	.14,.12
E	.05	<.01	--	.80	.29	.59	--	<.05	.10	.1	--
F	.04	<.01	.001	.83	.48	.57	--	.07	.08	.05	.09
Hand-Deboned Meat											
G	.02	<.01	.003,.001	.34	.21	.17	--	.07	<.05	.05	.04,.05
H	.02	<.01	<.001	.28	.16	.19	--	<.05	<.05	.4	.03
I	.03	<.01	.001	.25	.14	.19	--	.12	.08	.05	.07
J	.03	<.01	.007,.006	.28	.81	.16	--	N.D.	.07	.05	.05,.05

1 Atomic Absorption Spectrophotometry Method (Unpublished).
2 Atomic Absorption Spectrophotometry Method (Modified AOAC Procedure 25.065). The data for cadmium and lead used in the consumption studies were obtained by this method.
3 Anodic Stripping Voltametry Method.
4 Wisconsin Alumni Research Foundation.

Table IV-C-3 Comparison of Methods for Determining Fluoride Content of Mechanically Deboned Meat and Hand-Deboned Meat

Sample Description	Diffusion Method[1]		Diffusion Preceded by Dry Ashing	Fluoride Electrode Method[2]	
	FDA[3]	VA	VA	FDA	USDA
	ppm	ppm	ppm	ppm	ppm
Mechanically Deboned Meat:					
A	8.0	7.6	7.3	7.0, 6.1	7.8
B	9.4	10.6	10.8	8.3	10.8
C	10.8	7.6	--	5.8, 6.1	7.0
D	4.4	5.1	--	3.3	4.6
E	14.6	15.4	15.0	7.8	12.9
F	--	18.0	16.9	13.8	16.2
G	24.7	24.0	22.7	14.9, 15.2	27.2
H	28.4	31.2	30.2	19.0, 22.6	24.4
J	--	8.0	10.6	--	8.9
K	--	13.3	12.9	--	14.8
L	--	16.3	16.2	--	16.7
M	--	16.6	16.4	--	21.8
Hand-Deboned Meat					
J	--	--	--	0.84	1.4, 1.3
K	0.4	--	--	0.11, 0.17	0.6, 0.5
L	< 0.4	--	--	0.32, 0.28	0.4, 0.5
Mean of K, L	0.4	--	--	0.22	0.5

1 Method of Singer and Armstrong, Anal. Chem. 31 (1), 105-109, 1959.
2 Method of Dolan, et al., unpublished. Available on request from Food Safety and Quality Service, USDA.
3 Key to laboratories making analyses:
FDA = Food and Drug Administration laboratories, Washington, D.C.;
VA = Veterans Administration, Hines, IL;
USDA = Food Safety and Quality Service, Special Projects Laboratory, Washington, D.C.

APPENDIX V

CONSUMPTION DATA

A. EXPLANATION OF CONSUMPTION TABLES.

Values in the tables in V-B are derived from food intake data collected by the U.S. Department of Agriculture Household Food Consumption Survey (HFCS) in 1965 and from frequency of eating data collected by the Market Research Corporation of America (MRCA) in 1972-1973. These two surveys provide the most current data available for the purpose of estimating probable intake of foods or minerals in those foods among groups of individuals.

Data from the 1965 HFCS are for 1-day intakes of individuals collected in the spring (April, May and June), 1965. HFCS raw data provided ages of individuals which were used for classification, their body weights which were used to calculate exposure to minerals contained in Mechanically Deboned Meat (MDM), and quantitative data on how much food was eaten.

MRCA data provided information on how often foods were eaten by individuals for 14 consecutive days and were collected during the year of July 1, 1972, through June 30, 1973. MRCA's standard reference report which presents grouped data was used to obtain an average daily frequency of eating for the age groups of individuals for the MDM evaluation. The MRCA data applied to the HFCS make the adjusted food intakes more current and reflect a 2-week variability of eating patterns.

One objective of the MDM evaluation was to estimate the amount of mechanically deboned meat products (MDM) projected to be consumed. To accomplish this, it was necessary to identify the foods which were projected to contain MDM, to identify those who ate the MDM meat products, and to estimate the concentration of MDM in the final foods. Through this selection process, it is assumed that if health hazards were either controllable or negligible for those eating MDM formulated products, there would be no problem for the total population.

A detailed list of foods included in each meat group is given in Table V-B-1. Each food is identified with the 6-digit HFCS Survey food code. These items were judged to be the meat products in which use of MDM was technologically feasible.

Meat intake and MDM intake data, as shown in the tables, are based on a subsample of eaters only from the HFCS population. All table values are in terms of per kilogram of body weight. Average body weights for each age group are also given for those who wish to calculate values in terms of food quantities.

The selected subsample of eaters included only those who ate meat items in which MDM was proposed for use. As a result, approximately one-half of the HFCS population qualified as an eater of MDM products. The

counts for the subsample of eaters used in calculations by seven age groups, males and females combined, and proportions of the counterpart in the HFCS Survey are:

Age group	Counts of eaters*	MDM eaters as a % of USDA Survey Populations
years	number	percent
0-2	482	39.5
3-5	705	50.5
6-12	1,727	55.7
13-17	1,134	59.3
18-24	2,598	56.3
45 or more	2,678	50.8
Total	10,272	54.0

Intake estimates were made relative to the concentration of MDM in the food as eaten. The calculations were based on the assumption that the meat products contained MDM at a level of 20 percent of the meat content (or block) in the final food. Since many meat products are not 100 percent meat, the amounts of MDM varied as tabulated below:

Meat Product	Type of MDM	Percent of MDM
Baby-Junior Meats	Beef or pork	12
Hamburger	Beef	20
Cured meats	Pork	10
Sausages, general	Beef	17
Franks, bologna, vienna sausage	Beef	17
Fresh pork sausage (bulk and link)	Pork	19
Dry and semi-dry sausages	Beef	19
Dinners	Beef	5
Formulated products	Beef or Pork	4
Formulated products	Beef or Pork	9
Formulated products	Beef or Pork	15

*Counts of eaters are based on a weighted number of persons, 19,029 for all ages, in the HFCS Survey. Weighting of data is necessary to account for a sampling procedure used in data collection which included one-half of the persons between the ages of 20 to 64 years inclusive.

Based on these three factors (identification of MDM foods, sample of MDM eaters, and MDM concentrations), meat intake and MDM intake were calculated at two levels, the average and the probable maximum level or 90th percentile intake. When calculating average intake data, counts of eaters remained constant for total meat and each of the meat product subgroups within age groups. Data for meat subgroups have not been included in the tables because they were of limited usefulness in evaluating the safety of MDM. However, Tables V-B-2 and V-B-3 contain data on intakes of MDM for each age group with and without its presence in hamburger. For infants, data on projected intakes are reported with and without its presence in baby and junior foods, in hamburger, and in both meat groups. These data along with the data given in Table V-B-4 and V-B-5 are the primary consumption values used by the Panel in making its assessment.

In the selection process of the intake level for the 90th percentile of eaters, only individuals who reported eating a product within that meat subgroup were included in the quantitative array; the corresponding total meat products included all individuals who ate products from any one or more of the meat subgroups. Since the size of the eater population is not the same for the total and each meat group at the probable maximum intake level, values for the meat subgroups would not add to total meat products. Only summary lines, therefore, have been included in the tables on 90th percentile intakes of MDM products (Tables V-B-4 and V-B-5).

For all age groups except 0-2 years, no baby or junior foods were eaten at the 90th percentile level. Therefore, summary lines for "meat without baby-junior foods" and "meat without baby-junior foods and hamburger" have been omitted. Consumption values for these data lines would be the same as in "total meat" and "meat without hamburger," respectively.

Another objective of the MDM evaluation was to estimate the amount of minerals from MDM projected to be added to the diets at the two levels of food intake. Data on average and 90th percentile contents of minerals in mechanically deboned beef and pork as given below were used in making the calculations.

Element	MD Beef		MD Pork	
	Mean	90th Pct.	Mean	90th Pct.
Lead, mcg/g	0.09	0.03	0.06	0.10
Zinc, mcg/g	34.17	46.80	23.20	27.60
Calcium, %	.59	.86	.41	.69
Fluoride, mcg/g	18.60	27.80	11.00	18.30

Element	MD Beef		MD Pork	
	Mean	90th Pct.	Mean	90th Pct.
Iron, mcg/g	40.85	53.91	19.90	25.20
Nickel, mcg/g	.33	.44	.33	.49
Cadmium, mcg/g	< .01	<.01	<.01	<.01
Copper, mcg/g	.54	.75	.70	.85
Cobalt, mcg/g	.29	.42	.23	.37

The cadmium content used for calculating intakes, as presented in the above table, is at the level of analytical detectability. Because all analyses fell below this level, the data for cadmium represent the highest possible content, rather than the content to be expected at the average and 90th percentile levels of intake.

Applying the two levels of minerals to the appropriate food groups, consumption data were calculated for average and 90th percentile values for both MDM intake and mineral contents. Thus, in section V-B there are tables for average-average (Table V-B-2) and average-90th percentile (pct) (Table V-B-3), 90th pct-average (Table V-B-4), and 90th pct-90th pct (Table V-B-5) derived from the respective values for MDM intake times mineral content for MDM.

For all age groups, persons at the 90th percentile of estimated MDM intakes ate beef but not pork. Therefore, calculations for Tables V-B-4 and V-B-5 were made using data for beef MDM only. Had any proportion of the intakes been pork, intakes of all minerals except copper would have been lower than the tabulated values.

Calculations of consumption data included the following steps:

1. 132 food items in which use of MDM would be applicable were selected from HFCS's 1965 Survey code book and assigned to one of the meat product groups.

2. Consumption for each of the individuals from the HFCS 1965 Survey computer tape was checked for the selected MDM food items. During this process a subsample of eaters was selected. If a MDM food item was found, the consumption of that food item was summed into the applicable food group for that individual. It was found necessary to delete some of the pork products originally selected for study because these items were reported as eaten only once or twice.

3. A daily average frequency of eating for each meat group, derived from the MRCA standard reference report, was multiplied times each individual's consumption for each meat group to give an adjusted intake for each meat group per individual per day.

4. The adjusted intakes per day for all meat groups were then summed for each individual to give the adjusted total daily intake of products which could contain MDM.

5. Adjusted intakes, total and by meat group, for each individual were divided by that individual's weight to express data in terms of intake per kilogram of body weight. Average intakes of each meat group and of total meat groups were calculated on the basis of total eaters among each age range.

6. Adjusted total intakes (per kg of body weight) by individuals were arranged from smallest to largest within the seven age groups. The intake at the 90th percentile (9th decile) of eaters within a food group for each age group was selected from the appropriate array. As such, the 90th percentile level of intake represents the highest amount of adjusted intake reported by 90 percent of the eaters of MDM meat products or that level of intake equaled or exceeded by 10 percent of the eaters.

7. Data for intake of MDM were determined at the same time as data for consumption of meat groups and of total meat products. Estimates of intake for MDM were obtained by multiplying the percent of MDM in each food group times the adjusted intakes obtained in steps 3 and 4, then proceeding as described in steps 5 and 6.

8. Values for average mineral content and for 90th percentile mineral content were multiplied by the values for average adjusted intake of MDM and 90th percentile adjusted intake of MDM to produce estimates of intakes of the minerals as given in Tables V-B-2 through 5.

B. CONSUMPTION TABLES

Table V-B-1. FOOD CODES FROM THE 1965 USDA HOUSEHOLD FOOD CONSUMPTION SURVEY LISTED BY MDM MEAT PRODUCT CATEGORY

USDA FOOD CODE	BABY AND JUNIOR MEAT PRODUCTS--BEEF (12% MDM)
021101	Beef
021103	Beef with bacon
021105	Beef with beef heart
021107	Meat sticks
021111	Meat base formula
021226	Beef, junior
021230	Beef, baby or strained
022067	Frankfurters or meat sticks
022137	Frankfurters or meat sticks, baby or strained
022141	Frankfurters or meat sticks, junior
023013	Lamb, baby or junior
023017	Lamb, baby or strained
023113	Veal, baby or junior
023115	Veal, baby or strained
023117	Veal, junior
026701	Beef with vegetables
026702	Beef and noodles
026703	Beef liver soup
026704	Veal with vegetables
026750	Beef with vegetables or meat not specified
026751	Beef and noodles
026752	Beef liver soup
026753	Veal with vegetables

USDA FOOD CODE	BABY AND JUNIOR MEAT PRODUCTS--PORK (12% MDM)
022071	Ham
022073	Pork
022143	Ham, baby or strained
022145	Ham, junior
022147	Pork, baby or strained
022151	Pork, junior
026705	Ham with vegetables
026754	Ham with vegetables
026762	Bacon with vegetables

USDA FOOD CODE	
	HAMBURGER (20% BEEF MDM)
021023	Ground meat, broiled
021025	Ground meat, fried or grilled
021027	Beef, chopped canned
021033	Raw beef pattie
021125	Beef patty, lean, fried, grilled or cooked not specified
021127	Beef patty, broiled
021301	Beef, lunchmeat
023007	Lamb, ground or patty
023107	Veal, ground or patty
023119	Veal, chopped, breaded, fried
	CURED ITEMS (10% PORK MDM)
022013	Ham, cured, smoked
022017	Bacon, Canadian, cured (lean or fat)
022095	Ham, boiled
022096	Ham, boiled (lean)
022097	Ham, chopped, minced, spiced or unspiced (include spam, treet)
022101	Ham, deviled or potted
	SAUSAGES, GENERAL (17% BEEF MDM)
022077	Bockwurst, bratwurst, luncheon loaf, pork meat
022110	Luncheon loaf, not specified as to kind of meat *
022111	Luncheon loaf, not specified as to kind of meat *
022113	Mortadella *
022115	Polish style sausage
022075	Blood sausage, blood pudding, blutwurst *
022083	Braunschweiger
022103	Head cheese
022107	Liverwurst, liver cheese
022127	Scrapple
022131	Souse
022133	Thuringer pork roll
022125	Salami, cooked or not specified

* Frequencies of eating were accounted for in beef lunchmeat or in MDM meat product category, "Hamburger," so counts of frequency were excluded from MRCA data in this group.

USDA FOOD CODE	
	FRANKS (17% BEEF MDM)
022081	Bologna
022093	Frankfurters, hotdogs, wieners
022105	Knockwurst
022135	Vienna sausage
	FRESH PORK SAUSAGE (19% PORK MDM)
022117	Pork sausage, fresh bulk or link
022118	Pork sausage, fresh bulk or link
022121	Pork sausage country style or smoked
	DRY OR SEMI-DRY SAUSAGE (19% BEEF MDM)
022087	Cervelat, dry
022091	Cervelat, soft or not specified
022123	Salami, dry
	DINNERS (5% BEEF MDM)**
026601	Frozen TV dinner, Beef
026602	Frozen TV dinner, Beef pot roast
026608	Frozen TV dinner, Corned beef hash
026625	Frozen TV dinner, Salisbury steak
026634	Frozen TV dinner, Sukiyaki
026638	Frozen TV dinner, Ham
	FORMULATED MEAT PRODUCTS CONTAINING NO MORE THAN 4% MDM (4% BEEF MDM)
026002	Cabbage rolls
026005	Chop suey, any kind of meat
026006	Chow mein, any kind of meat
026008	Creamed chipped beef
026018	Creamed dried beef on toast
026029	Wieners and sauerkraut
026040	Chow mein with pork
026047	Stuffed pepper

** When selecting beef and pork MDM values for application to the groups, we found in MRCA data that total eating of this group equaled 608. All but 39 were beef. Therefore, we decided to use beef MDM values for the entire dinner group.

USDA FOOD CODE	FORMULATED MEAT PRODUCTS CONTAINING FROM 5 TO AND INCLUDING 9% MDM (9% BEEF MDM)
026001	Beef pot pie
026003	Chili con carne with beans
026004	Chili con carne without beans
026007	Corned beef hash
026009	Goulash
026012	Roast beef hash
026014	Shepherd's pie
026016	Stew, any meat with vegetables
026017	Stew, any meat without vegetables
026020	Chorizos (hard salami with eggs)
026022	Beef stroganoff, creamed meat
026025	Ham salad, pork salad
026030	Ham with vegetables
026032	Beef stew with bone
026034	Pork and ham in gravy
026035	Beef and noodles, with or without tomatoes
026036	Beef and rice mixture with or without tomatoes

	FORMULATED MEAT PRODUCTS CONTAINING FROM 10 TO AND INCLUDING 15% MDM (15% BEEF MDM)
026010	Meat loaf, beef or ham
026011	Pork or beef and gravy
026013	Salisbury steak
026023	Meat other than ham or pork and barbecue sauce
026027	Ground meat with pumpkin
026033	Pork and ham in barbecue sauce
026024	Ham and cheese, pork and cheese, pork bologna, and cheese
026031	Beef loaf
026037	Salami and cheese
026038	Wieners and cheese with or without bacon
026039	Beef with green peppers
026042	Beef frankfurters in sauce
026043	Pork, rice, bean mixture
026044	Liver hash
026045	Chopped meat surplus and other (Food Donation Program)
026048	Beef loaf
026049	Beef and gravy

Table V-B-2

PROBABLE MAXIMUM FOOD EXPOSURE TO MDM AND INCREASE IN EXPOSURE TO NINE ELEMENTS IN MDM
FOR DIFFERENT AGE GROUPS OF EATERS OF MDM-CONTAINING FOOD PRODUCTS
MDM CONTENT SET AT 20% OF THE MEAT BLOCK
AVERAGE MDM INTAKE TIMES AVERAGE METAL BY AGE GROUP
(M R C A FREQUENCY ADJUSTED VALUES PER KILOGRAM BODY WEIGHT)

AGE RANGE (yrs)	BODY WEIGHT (kg)	GROUP NAME	MEAT INTAKE (g)	MDM INTAKE (mg)	LEAD (mcg)	ZINC (mcg)	CALCIUM (mg)	FLUORIDE (mcg)	IRON (mcg)
0-2	12.194	TOTAL MEAT[2]	.376	51.822	.00453	1.72355	.29800	.93118	2.02678
		MEAT W/O BABY-J	.132	22.439	.00198	.75553	.13054	.40959	.89519
		MEAT W/O HAMBGR	.324	41.388	.00359	1.36702	.23644	.73711	1.60055
		MEAT W/O B-J/HB	.079	12.006	.00104	.39900	.06898	.21552	.46897
3-5	17.911	TOTAL MEAT[2]	.356	62.463	.00553	2.10105	.36305	1.13873	2.48800
		MEAT W/O HAMBGR	.199	31.009	.00269	1.02630	.17748	.55371	1.20315
6-12	32.710	TOTAL MEAT[2]	.363	62.538	.00551	2.09749	.36249	1.13589	2.47938
		MEAT W/O HAMBGR	.200	29.803	.00257	.97894	.16936	.52702	1.14215
13-17	56.129	TOTAL MEAT[2]	.277	47.217	.00412	1.56705	.27097	.84612	1.84030
		MEAT W/O HAMBGR	.140	19.749	.00165	.62847	.10891	.33522	.71823
18-24	65.310	TOTAL MEAT[2]	.206	36.563	.00319	1.21441	.20998	.65586	1.42687
		MEAT W/O HAMBGR	.079	11.183	.00091	.34721	.06024	.18381	.39014
25-44	70.153	TOTAL MEAT[2]	.191	32.560	.00284	1.08134	.18697	.58397	1.27043
		MEAT W/O HAMBGR	.091	12.699	.00105	.40269	.06979	.21456	.45910
45+	71.325	TOTAL MEAT[2]	.152	25.969	.00222	.84685	.14656	.45496	.98348
		MEAT W/O HAMBGR	.069	9.391	.00073	.28038	.04875	.14661	.30627

Table V-B-2 (Continued)

AGE RANGE (yrs)	BODY WEIGHT (kg)	GROUP NAME	MEAT INTAKE (g)	MDM INTAKE (mg)	NICKEL (mcg)	CADMIUM[1] (mcg)	COPPER (mcg)	COBALT (mcg)
0-2	12.194	TOTAL MEAT[2]	.376	51.822	.01710	<.00051	.02867	.01476
		MEAT W/O BABY-J	.132	22.439	.00740	<.00022	.01228	.00644
		MEAT W/O HAMBGR	.324	41.388	.01365	<.00041	.02303	.01174
		MEAT W/O B-J/HB	.079	12.006	.00396	<.00011	.00664	.00341
3-5	17.911	TOTAL MEAT[2]	.356	62.463	.02061	<.00062	.03421	.01793
		MEAT W/O HAMBGR	.199	31.009	.01023	<.00030	.01723	.00881
6-12	32.710	TOTAL MEAT[2]	.363	62.538	.02063	<.00062	.03434	.01791
		MEAT W/O HAMBGR	.200	29.803	.00983	<.00029	.01666	.00842
13-17	56.129	TOTAL MEAT[2]	.277	47.217	.01558	<.00047	.02617	.01343
		MEAT W/O HAMBGR	.140	19.749	.00651	<.00019	.01133	.00547
18-24	65.310	TOTAL MEAT[2]	.206	36.563	.01206	<.00036	.02025	.01041
		MEAT W/O HAMBGR	.079	11.183	.00369	<.00011	.00654	.00305
25-44	70.153	TOTAL MEAT[2]	.191	32.560	.01074	<.00032	.01803	.00927
		MEAT W/O HAMBGR	.091	12.699	.00419	<.00012	.00731	.00351
45+	71.325	TOTAL MEAT[2]	.152	25.969	.00856	<.00025	.01461	.00730
		MEAT W/O HAMBGR	.069	9.391	.00309	<.00009	.00566	.00250

[1]Cadmium values were calculated at the level of detectability (.01 mcg/g), although all analyses were below that amount.

[2]"Total Meat" means the total amount of meat food products containing MDM.

Table V-B-3

PROBABLE MAXIMUM FOOD EXPOSURE TO MDM AND INCREASE IN EXPOSURE TO NINE ELEMENTS IN MDM
FOR DIFFERENT AGE GROUPS OF EATERS OF MDM-CONTAINING FOOD PRODUCTS
MDM CONTENT SET AT 20% OF THE MEAT BLOCK
AVERAGE MDM INTAKE TIMES 90th PERCENTILE METAL BY AGE GROUP
(M R C A FREQUENCY ADJUSTED VALUES PER KILOGRAM BODY WEIGHT)

AGE RANGE (yrs)	BODY WEIGHT (kg)	GROUP NAME	MEAT INTAKE (g)	MDM INTAKE (mg)	LEAD (mcg)	ZINC (mcg)	CALCIUM (mg)	FLUORIDE (mcg)	IRON (mcg)
0-2	12.194	TOTAL MEAT[2]	.376	51.822	.00660	2.34265	.43835	1.39977	2.67018
		MEAT W/O BABY-J	.132	22.439	.00288	1.03051	.19123	.61409	1.18031
		MEAT W/O HAMBGR	.324	41.388	.00525	1.85434	.34862	1.10970	2.10768
		MEAT W/O B-J/HB	.079	12.006	.00152	.54220	.10150	.32402	.61781
3-5	17.911	TOTAL MEAT[2]	.356	62.463	.00802	2.86497	.53201	1.70762	3.28021
		MEAT W/O HAMBGR	.199	31.009	.00393	1.39297	.26151	.83323	1.58458
6-12	32.710	TOTAL MEAT[2]	.363	62.538	.00802	2.85777	.53170	1.70441	3.26823
		MEAT W/O HAMBGR	.200	29.803	.00376	1.32577	.25018	.79438	1.50349
13-17	56.129	TOTAL MEAT[2]	.277	47.217	.00601	2.12863	.39888	1.27249	2.42416
		MEAT W/O HAMBGR	.140	19.749	.00244	.84313	.16265	.50888	.94336
18-24	65.310	TOTAL MEAT[2]	.206	36.563	.00465	1.64999	.30902	.98619	1.87966
		MEAT W/O HAMBGR	.079	11.183	.00135	.46255	.09076	.28065	.51148
25-44	70.153	TOTAL MEAT[2]	.191	32.560	.00414	1.46914	.27517	.87812	1.67357
		MEAT W/O HAMBGR	.091	12.699	.00156	.53965	.10436	.32598	.60286
45+	71.325	TOTAL MEAT[2]	.152	25.969	.00326	1.14446	.21705	.68686	1.29399
		MEAT W/O HAMBGR	.069	9.391	.00110	.36861	.07448	.22599	.40027

Table V-B-3 (Continued)

AGE RANGE (yrs)	BODY WEIGHT (kg)	GROUP NAME	MEAT INTAKE (g)	MDM INTAKE (mg)	NICKEL (mc)	CADMIUM[1] (mcg)	COPPER (mcg)	COBALT (mcg)
0-2	12.194	TOTAL MEAT[2]	.376	51.822	.02301	<.00051	.03929	.02154
		MEAT W/O BABY-J	.132	22.439	.00992	<.00022	.01693	.00937
		MEAT W/O HAMBGR	.324	41.388	.01842	<.00041	.03147	.01716
		MEAT W/O B-J/HB	.079	12.006	.00533	<.00011	.00910	.00499
3-5	17.911	TOTAL MEAT[2]	.356	62.463	.02763	<.00062	.04715	.02608
		MEAT W/O HAMBGR	.199	31.009	.01379	<.00030	.02356	.01287
6-12	32.710	TOTAL MEAT[2]	.363	62.538	.02769	<.00062	.04726	.02608
		MEAT W/O HAMBGR	.200	29.803	.01329	<.00029	.02271	.01233
13-17	56.129	TOTAL MEAT[2]	.277	47.217	.02098	<.00047	.03583	.01961
		MEAT W/O HAMBGR	.140	19.749	.00890	<.00019	.01523	.00808
18-24	65.310	TOTAL MEAT[2]	.206	36.563	.01624	<.00036	.02774	.01519
		MEAT W/O HAMBGR	.079	11.183	.00507	<.00011	.00870	.00453
25-44	70.153	TOTAL MEAT[2]	.191	32.560	.01446	<.00032	.02470	.01353
		MEAT W/O HAMBGR	.091	12.699	.00572	<.00012	.00980	.00519
45+	71.325	TOTAL MEAT[2]	.152	25.969	.01161	<.00025	.01984	.01072
		MEAT W/O HAMBGR	.069	9.391	.00431	<.00009	.00741	.00375

[1]Cadmium values were calculated at the level of detectability (.01 mcg/g), although all analyses were below that amount

[2]"Total Meat" means the total amount of meat food products containing MDM.

Table V-B-4
PROBABLE MAXIMUM FOOD EXPOSURE TO MDM AND INCREASE IN EXPOSURE TO NINE ELEMENTS IN MDM
FOR DIFFERENT AGE GROUPS OF EATERS OF MDM-CONTAINING FOOD PRODUCTS
MDM CONTENT SET AT 20% OF THE MEAT BLOCK
90th PERCENTILE MDM INTAKE TIMES AVERAGE METAL BY AGE GROUP
(M R C A FREQUENCY ADJUSTED VALUES PER KILOGRAM BODY WEIGHT)

Age Range	Body Weight	Group Name	Meat Intake	MDM Intake	Lead	Zinc	Calcium	Fluoride	Iron
(yrs)	(kg)		(g)	(mg)	(mcg)	(mcg)	(mg)	(mcg)	(mcg)
0-2	12.194	Total Meat[2]	1.279	153.510	.01381	5.24543	.90570	2.85528	6.27088
		Meat w/o Baby-J	.320	60.148	.00541	2.05526	.35487	1.11875	2.45705
		Meat w/o Hambgr	1.122	134.681	.01212	4.60205	.79461	2.50507	5.50172
		Meat w/o B-J, HB	.194	33.029	.00297	1.12860	.19487	.61434	1.34923
3-5	17.911	Total Meat[2]	.719	134.985	.01215	4.61244	.79641	2.51072	5.51414
		Meat w/o Hambgr	.457	73.334	.00660	2.50582	.43267	1.36401	2.99569
6-12	32.710	Total Meat[2]	.813	145.119	.01306	4.95872	.85620	2.69921	5.92811
		Meat w/o Hambgr	.490	76.429	.00688	2.61158	.45093	1.42158	3.12213
13-17	56.129	Total Meat[2]	.583	107.470	.00967	3.67225	.63407	1.99894	4.39015
		Meat w/o Hambgr	.333	49.735	.00448	1.69944	.29344	.92507	2.03168
18-24	65.310	Total Meat[2]	.506	96.399	.00867	3.29395	.56875	1.79302	3.93790
		Meat w/o Hambgr	.200	27.201	.00245	.92946	.16049	.50594	1.11116
25-44	70.153	Total Meat[2]	.430	80.556	.00724	2.75260	.47528	1.49834	3.29071
		Meat w/o Hambgr	.220	30.403	.00274	1.03887	.17938	.56550	1.24196
45 +	71.325	Total Meat[2]	.345	65.235	.00586	2.22908	.38489	1.21337	2.66485
		Meat w/o hambgr	.164	22.248	.00200	.76021	.13126	.41381	.90883

Table V-B-4 (Continued)

Age Range	Body Weight	Group Name	Meat Intake	MDM Intake	Nickel	Cadmium[1]	Copper	Cobalt
(yrs)	(kg)		(g)	(mg)	(mcg)	(mcg)	(mcg)	(mcg)
0-2	12.194	Total Meat[2]	1.279	153.510	.05065	<.00153	.08289	.04451
		Meat w/o Baby-J	.320	60.148	.01985	<.00060	.03248	.01744
		Meat w/o Hambgr	1.122	134.681	.04444	<.00135	.07273	.03906
		Meat w/o B-J, HB	.194	33.029	.01090	<.00033	.01784	.00958
3-5	17.911	Total Meat[2]	.719	134.985	.04454	<.00135	.07289	.03915
		Meat w/o Hambgr	.457	73.334	.02420	<.00073	.03960	.02127
6-12	32.710	Total Meat[2]	.813	145.119	.04788	<.00145	.07836	.04209
		Meat w/o Hambgr	.490	76.429	.02522	<.00076	.04127	.02216
13-17	56.129	Total Meat[2]	.583	107.470	.03546	<.00108	.05803	.03117
		Meat w/o Hambgr	.333	49.735	.01641	<.00050	.02686	.01442
18-24	65.310	Total Meat[2]	.506	96.399	.03181	<.00097	.05205	.02796
		Meat w/o Hambgr	.200	27.201	.00898	<.00027	.01469	.00789
25-44	70.153	Total Meat[2]	.430	80.556	.02658	<.00081	.04350	.02336
		Meat w/o Hambgr	.220	30.403	.01003	<.00030	.01642	.00882
45 +	71.325	Total Meat[2]	.345	65.235	.02153	<.00066	.03523	.01892
		Meat w/o hambgr	.164	22.248	.00734	<.00022	.01202	.00645

[1]Cadmium values were calculated at the level of detectability (.01 mcg/g), although all analyses were below that amount.

[2]"Total Meat" means the total amount of meat food products containing MDM.

Table V-B-5

PROBABLE MAXIMUM FOOD EXPOSURE TO MDM AND INCREASE IN EXPOSURE TO NINE ELEMENTS IN MDM FOR DIFFERENT AGE GROUPS OF EATERS OF MDM-CONTAINING FOOD PRODUCTS

MDM CONTENT SET AT 20% OF THE MEAT BLOCK

90th PERCENTILE MDM INTAKE TIMES 90th PERCENTILE METAL BY AGE GROUP

(M R C A FREQUENCY ADJUSTED VALUES PER KILOGRAM BODY WEIGHT)

Age Range	Body Weight	Group Name	Meat Intake	MDM Intake	Lead	Zinc	Calcium	Fluoride	Iron
(yrs)	(kg)		(g)	(mg)	(mcg)	(mcg)	(mg)	(mcg)	(mcg)
0-2	12.194	Total Meat[2]	1.279	153.510	.01995	7.18426	1.32018	4.26757	8.27572
		Meat w/o Baby-J	.320	60.148	.00782	2.81492	.51727	1.67211	3.24258
		Meat w/o Hambgr	1.122	134.681	.01750	6.30306	1.15825	3.74412	7.26065
		Meat w/o B-J, HB	.194	33.029	.00429	1.54576	.28405	.91820	1.78059
3-5	17.911	Total Meat[2]	.719	134.985	.01755	6.31730	1.16087	3.75258	7.27704
		Meat w/o Hambgr	.457	73.334	.00953	3.43203	.63067	2.03868	3.95344
6-12	32.710	Total Meat[2]	.813	145.119	.01886	6.79157	1.24802	4.03431	7.82336
		Meat w/o Hambgr	.490	76.429	.00993	3.57688	.65729	2.12472	4.12029
13-17	56.129	Total Meat[2]	.583	107.470	.01397	5.02960	.92424	2.98767	5.79371
		Meat w/o Hambgr	.333	49.735	.00646	2.32760	.42772	1.38262	2.68122
18-24	65.310	Total Meat[2]	.506	96.399	.01253	4.51147	.82903	2.67989	5.19687
		Meat w/o Hambgr	.200	27.201	.00353	1.27301	.23393	.75618	1.46641
25-44	70.153	Total Meat[2]	.430	80.556	.01047	3.77002	.69278	2.23946	4.34277
		Meat w/o Hambgr	.220	30.403	.00395	1.42285	.26146	.84520	1.63903
45 +	71.325	Total Meat[2]	.345	65.235	.00848	3.05300	.56102	1.81353	3.51682
		Meat w/o hambgr	.164	22.248	.00289	1.04121	.19133	.61849	1.19939

Table V-B-5 (continued)

Table V-B-5 (Continued)

Age Range	Body Weight	Group Name	Meat Intake	MDM Intake	Nickel	Cadmium[1]	Copper	Cobalt
(yrs)	(kg)		(g)	(mg)	(mcg)	(mcg)	(mcg)	(mcg)
0-2	12.194	Total Meat[2]	1.279	153.510	.06754	<.00153	.11513	.06447
		Meat w/o Baby-J	.320	60.148	.02646	<.00060	.04511	.02526
		Meat w/o Hambgr	1.122	134.681	.05926	<.00134	.10101	.05657
		Meat w/o B-J, HB	.194	33.029	.01453	<.00033	.02477	.01387
3-5	17.911	Total Meat[2]	.719	134.985	.05939	<.00135	.10124	.05669
		Meat w/o Hambgr	.457	73.334	.03227	<.00073	.05500	.03080
6-12	32.710	Total Meat[2]	.813	145.119	.06385	<.00145	.10884	.06095
		Meat w/o Hambgr	.490	76.429	.03363	<.00076	.05732	.03210
13-17	56.129	Total Meat[2]	.583	107.470	.04729	<.00107	.08060	.04514
		Meat w/o Hambgr	.333	49.735	.02188	<.00050	.03730	.02089
18-24	65.310	Total Meat[2]	.506	96.399	.04242	<.00096	.07230	.04049
		Meat w/o Hambgr	.200	27.201	.01197	<.00027	.02040	.01142
25-44	70.153	Total Meat[2]	.430	80.556	.03544	<.00080	.06042	.03383
		Meat w/o Hambgr	.220	30.403	.01338	<.00030	.02280	.01277
45 +	71.325	Total Meat[2]	.345	65.235	.02870	<.00065	.04893	.02740
		Meat w/o hambgr	.164	22.248	.00979	<.00022	.01668	.00934

[1]Cadmium values were calculated at the level of detectability (.01 mcg/g), although all analyses were below that amount.

[2]"Total Meat" means the total amount of meat food products containing MDM.

APPENDIX VI
SUMMARIES OF PANEL MEETINGS

SUMMARY OF THE FIRST MEETING OF THE
SELECT PANEL ON THE HEALTH AND SAFETY ASPECTS
OF THE USE OF MECHANICALLY DEBONED MEAT

The first interagency meeting on the health and safety aspects of the use of mechanically deboned meat (MDM) convened at 9:30 a.m. on Friday, October 8, 1976. A list of the attendees is attached. Dr. Kolbye and Dr. Nelson served as co-chairmen of the meeting. General remarks were made concerning the need for counsel from the group by Drs. Kolbye, Nelson, and Houston.

Mr. Dennis and Dr. Houston then related the background that preceded the meeting. At this time, the use of mechanically deboned red meat is illegal because of the U.S. District Court Preliminary Injunction issued on September 10, 1976. The reasons given for the injunction were that the United States Department of Agriculture (USDA) did not follow administrative procedures in issuing the interim regulation by not providing an opportunity for public review and comment; and furthermore, did not adequately assess the health aspects of MDM in regard to possible gastroenterological side effects of bone particle ingestion, the possible high levels of Strontium-90, and long term effect of the fat content on cardiovascular systems.

It was clarified that only the interim regulation concerning mechanically deboned and low temperature rendered meats published on April 27, 1976, was struck down by the judge's ruling. The Definition of Meat proposal published at the same time was not affected by the ruling. Efforts of the group should be directed toward the proposed regulation. At the present time over 1,000 comments have been received on the proposed regulation on classes of meat. Many of the comments pertained to the "bone chip" issue. However, this was generally considered a moot issue with MDM because of the processing procedure involved. Other health and safety issues that received comments concerned possible mechanical irritation of the g.i. tract by bone particles, the high calcium content, protein quality, and trace metal content; viz., lead and fluoride. The extent of documentation regarding health problems associated with the ingestion of MDM was sparse, and the accumulation of documentation is, it was agreed, a primary task of the group. In addition to the information available, USDA is having tests conducted to determine the protein quality, and the lead, fluoride, calcium, and zinc content of MDM.

A question was raised concerning the extent of documentation regarding health problems of mechanically deboned poultry and fish protein concentrate, which have been utilized as food ingredients for a number of years. The group was not aware of extensive documentation. With regard to strontium-90 content, mechanically deboned poultry was not considered to pose a health problem at the time of introduction into the marketplace.

The following areas and questions were considered as pertinent and in need of further documentation and study.

1. Bone particle size in MDM

   Is it a hazard?
   If so, could anything be done to make it nonhazardous?

   How uniform is the particle size among various makes of deboning equipment?

   How available is the bone calcium?

Calcium gluconate tablets and bone meal were mentioned as being consumed in this country without apparent deleterious effects. Also, in the U.K. and Newfoundland bone meal has been used in foods for some time, and it was thought an exploration of their experiences might prove useful. Both abnormal as well as normal gastrointestinal conditions were thought to be important considerations. The glass and cellulose feeding studies were also thought to be areas worthy of investigation.

2. Calcium in MDM

   Is it a nutritional benefit or health hazard?

   If a benefit, are the proposed limits on calcium content proper and realistic?

   If a hazard, are there conditions under which it will cease to be a hazard?

   To what extent should calcium:phosphorus ratios be of concern in this product?

The potential problems of kidney stones and hypocalcemia were considered as subjects to be investigated. There was some mention of having more information about the bone marrow content of MDM and its effect on the finished product. The calcium limits, it was stated, were imposed to insure a good mechanical deboning operation and to prevent bone from being a filler.

3. Trace Elements

   Lead

   Are data on lead levels adequate? If not, what additional data are needed?

Do current data indicate that lead is a hazard? For what groups?

Are lead levels in MDM high enough to make this a product that cannot be used in commerce?

Should limits be set on MDM usage? Would such limits be effective in controlling excessive intakes in lead?

Fluoride

Are data on fluoride levels adequate? If not, what additional data are needed?

Do current data indicate that fluoride is a hazard? For what groups?

Are fluoride levels in MDM high enough to make this a product that cannot be used in commerce?

Should limits be set on MDM usage? Would such limits be effective in controlling excessive intakes of fluoride?

Strontium-90

Are levels of Strontium-90 in MDM a hazard?

Other Mineral Elements

Is there any reason to expect the presence of other toxic elements?

For elements such as zinc and selenium, which are both essential and hazardous, does MDM present any problems?

For elements such as iron and magnesium, are there nutritional advantages?

4. Lipids in MDM

Cholesterol

Are data on cholesterol adequate for evaluating its possible effects? If not, what additional data are needed?

Do cholesterol levels in MDM constitute a health hazard?

Should limits be set on MDM usage? Would such limits be effective in controlling excessive intakes of cholesterol?

Other Lipids

Are data adequate for evaluating MDM in terms of possible usage?

Do lipid components provide any nutritional advantages or disadvantages, if MDM should be allowed in products?

Lipid Residues

What types of residues are present? Carcinogenic?

5. Protein and Protein Quality in MDM

Should any parameters be established for protein quantity and quality?

If so, are the proposed standards for minimum protein content and protein quality reasonable and adequate?

Are measures for evaluating protein quality suitable?

It was decided because of the scope of the task that individual members of the group would be responsible for the accumulation of data and the developing of a position in an area of concern. The chairpersons and the areas of responsibility were designated as follows:

Effects of Bone Particle Size	Dr. Kolbye, FDA
Calcium as a Nutrient and A Possible Hazard	Dr. Spencer, VA
Lead as a Possible Hazard	Dr. Mahaffey, FDA
Fluoride as a Possible Hazard	Dr. Spencer, VA
Strontium-90 as a Possible Hazard	Dr. Engel, APHIS
Zinc, Selenium, Iron and Magnesium as Nutrients	Dr. Mattie Ray Spivey Fox, FDA, and Dr. Walter Mertz, Chairman, Nutrition Institute, ARS
Lipids--Nutrition and Health Aspects	Dr. Judd, ARS, and Dr. Combs, National Institute of Arthritis, Metabolism, and Digestive Diseases
Chlorinated Hydrocarbon Residues	Dr. Engel, APHIS
Protein and Protein Quality	Mr. Fried, APHIS with input from Dr. Forbes, FDA, and Dr. Naghski, ARS

The subcommittees are expected to review all available information, consult experts both within and outside the Federal Government and prepare reports of their findings. A list of all contacts should be kept.

In addition, Dr. Forbes offered the expertise and computer facilities of FDA in determining expected maximum reasonable consumption figures for various age and sex groups and the subsequent derivations of the safety and nutritive contributions of MDM. Dr. Forbes reiterated the need for extensive and valid data especially with respect to calcium, lead, and fluoride. APHIS will be furnishing Dr. Forbes information concerning types of products MDM may be used in, the level allowed, and the mineral concentrations in MDM. At this time, it was considered most feasible to limit the consumption studies to a limited number of products such as franks, bologna, and whole hog sausage in which MDM was mainly used.

Mrs. Murphy will be the coordinator for the group. She is responsible for disseminating literature, laboratory data, and the names of experts in areas of interest. Members of the group are to identify to Mrs. Murphy as soon as possible names of experts who would be knowledgeable in the areas of concern.

The time needed to complete the project was discussed at some length, but a deadline was not set. At the next meeting a draft of the report or at least a detailed outline should be completed for discussion. Copies of the draft or outline should be made available a few days before the meeting to other members of the group. The next plenary session will be held on Friday, November 19.

ATTENDEES AT THE FIRST MEETING OF THE SELECT PANEL ON THE HEALTH AND SAFETY ASPECTS OF THE USE OF MECHANICALLY DEBONED MEAT (MDM)

Mr. C. Ronald Brewington
Meat and Poultry Inspection Program

Dr. Gerald F. Combs
National Institute of Arthritis,
Metabolism, and Digestive Diseases

Mr. Bill Dennis
Meat and Poultry Inspection Program

Dr. Ronald Engel
Meat and Poultry Inspection Program

Dr. Allan Forbes
Food and Drug Administration

Mr. Irwin Fried
Meat and Poultry Inspection Program

Dr. Donald Houston
Meat and Poultry Inspection Program

Dr. Joseph Judd
Agriculture Research Service

Dr. Albert Kolbye
Food and Drug Administration

Dr. Kathryn Mahaffey
Food and Drug Administration

Mrs. Elizabeth Murphy
Meat and Poultry Inspection Program

Dr. Joseph Naghski
Agriculture Research Service

Dr. Merlin A. Nelson
Meat and Poultry Inspection Program

Dr. Herta Spencer
Veterans Administration

SUMMARY OF THE SECOND MEETING OF THE
SELECT PANEL ON THE HEALTH AND
SAFETY ASPECTS OF MECHANICALLY DEBONED MEAT

The second interagency meeting on the health and safety aspects of the use of mechanically deboned meat (MDM) convened at 9 a.m. on Friday, November 19, 1976. The attendees of the meeting, including observers from the USDA Food Safety Committee, introduced themselves. A list of the attendees is attached.

The results of the findings of each subcommittee were then reported.

Effects of Bone Particle Size Dr. Kolbye reported that he was not prepared to offer a draft or results at this time. He had received the results of the analyses on bone particle size, and the evaluation of these data would be completed in a few weeks. It was felt, however, that there should not be any significant problems.

Calcium as a Nutrient and a Possible Hazard Dr. Spencer related that, though the official RDA for calcium is 800 mg, recent calcium balance studies have shown that 50 percent of the adult subjects were in negative calcium balance on this calcium intake. A higher intake of calcium, 1,200 mg/day, is believed more desirable, having resulted in subjects with an average positive calcium balance. At levels above 1,200 mg/day, and up to 2,200 mg/day, subjects did not utilize the additional calcium, indicating the additional calcium is not needed and is, therefore, excreted. It was pointed out that this information pertained to normal subjects. Persons who are hyperabsorbers of calcium would be prone to kidney stone formation and should refrain from consuming MDM. However, in these cases the cause is not the diet, but a metabolic condition.

Calculations giving the calcium contribution from 2 franks and 2 oz. of bologna were presented. An additional 180 mg/day of calcium would be expected; and if added to the 800 mg/day RDA, which one may assume to be consumed, would give a total of approximately 1 gram of calcium/day, which is still within the 1,200 mg/day believed optimum. In view of the fact that certainly some individuals have insufficient intake of calcium and others avoid milk because of high cholesterol fears, the additional calcium from MDM was considered generally beneficial.

The need to modify slightly the calculations by adjusting the weight of the frank and using a meat content of 85 percent was discussed. Discussion also addressed the need for calcium labeling in the finished product, especially in view of the problems of hyperabsorbers of calcium. Three possible approaches were discussed including simply labeling MDM as such to alert the consumer to its presence, the labeling of the calcium content, and the labeling of product as containing more or less calcium than expected. It was decided that the entire question of

labeling MDM should be deferred and addressed as a separate issue on a larger scope. The question of bioavailability was raised but it was agreed that calcium in MDM should be as bioavailable as in fish protein concentrate. Documentation, however, is lacking.

Lead as a Possible Hazard - Dr. Mahaffey stated her reluctance to discuss lead in the absence of food consumption studies. The data from USDA to date show 90th percentile figures for lead to be in excess of 1 ppm. Using this as a basis, an additional 10 ug/day, 29 ug/day, and 64 ug/day can be expected to be ingested by 6-month-old infants, 2-year-old children, and adults respectively. The maximum permissible intake is considered to be 100-120 ug/day for 6-month-old infants, 150 ug/day for 2-year-old children, and 200 ug/day for 4 to 6-year-old children. Estimates of intake now show that 6-month-old infants consume 100-200 ug/day, 2-year-old children 75 ug/day, and adults 150-250 ug/day. The World Health Organization considers 430 ug/day the maximum acceptable intake for an adult. Thus, the additional lead provided by MDM may pose a problem for infants and very young children.

Discussion revealed that the lead intakes for infants and children were made several years ago and that, on the average, the consumption of lead is decreasing. A comparison was made between the contributions of lead by milk and MDM. Though the calcium to lead ratio in milk is threefold that of MDM, it was pointed out the absolute levels consumed would be indicative of risks. It was also pointed out that the real question is whether or not there is an incremental increase in lead intakes as a result of using MDM, keeping in mind that the meat being replaced also contains lead.

The effect of calcium on lead absorption was thought small, though studies are ongoing.

Fluoride as a Possible Hazard - Dr. Spencer reported that presently there is no definitive RDA for fluoride, which is considered an essential trace element. There is a general belief that the fluoride content of foods is less than it actually is because of studies done before the fluoridation of water. Recent actual intakes of 1.5 - 2 mg/day, exclusive of water, have been found. However, it is not unlikely to find levels ingested of 4 - 4.5 mg/day in fluoridated areas; even levels of 6-7 g/day are possible. It was pointed out that there does not exist a correlation between the fluoride content of the diet and the water in fluoridated and nonfluoridated areas.

Using data from USDA showing the fluoride content of MDM to be 5 ppm, about 0.18 mg of fluoride would be added to daily diet from 2 franks and 2 oz. of bologna. Using more recent data, with 1 out of 12 samples of MDM containing a high of 30 ppm, an additional 1 mg/day would be added to the daily diet. However, this additional fluoride was considered not hazardous and easily handled by individuals with normal kidney functions.

There are, however, two groups for which MDM ingestion may pose problems (1) patients with chronic renal disease who are unable to excrete fluoride normally, and (2) children below the age of 8 years because of possible mottling of teeth. With regard to baby foods, it was felt this should be considered separately since it is believed that baby foods contain adequate amounts of fluoride, and the intake of fluoride per kg of body weight is already high in relation to the diet.

The point was made that the fluoride content of the food MDM replaces must also be considered, and there is a need to obtain information on the average weekly intake of fluoride of an adult on a diet with and without MDM. Several comparisons were made between the fluoride content of MDM and other foods. Fish is recognized as containing more fluoride, but it was pointed out it was unlikely MDM would replace fish in the diet. The data accumulated to date show hand deboned meat containing about a tenth as much fluoride as MDM. A can of soft drink contains as much fluoride as one frank containing MDM. A regulation on fish protein concentrate restricts the fluoride content in the finished food to 8 ppm. If MDM contained 30 ppm and was used as a 20 percent replacement, only 6 ppm would be provided by MDM in a product.

The levels required to effect fluorosis were discussed at some length. It was stated that 10-20 mg for 10-20 years would result in bone changes, but levels promoting sub-fluorosis conditions were not known. In the Chicago area, Dr. Spencer has followed individuals consuming 5 to 6 mg of fluoride per day for 12 years without detecting any effect. The industrial maximum permissible level was believed to be 6 mg/day. An AMA statement was recalled that referred to levels in excess of 4-5 mg/day causing dental fluorosis and a level of 10 mg/day causing clinical fluorosis. However, this information was to be checked. An outbreak of massive fluorosis occurred in India at 9-10 mg/day, it was thought.

The concern was expressed that, similar to iodine, there is a continuing increase of fluoride in the diet coming from a number of sources, and there may be a need to curtail any additional sources. However, it was again stated that persons with normal kidney functions would have no trouble in handling the additional fluoride.

Finally, it was pointed out that the National Health Federation and Prevention magazine have been launching a massive campaign to have fluoridation of water banned on the basis that fluorine is a carcinogen. It was stated the group is very influential, as indicated by the fact Los Angeles no longer uses fluoridated water.

Strontium - 90 as a Possible Hazard - Dr. Engle also stated that without food consumption data a conclusion was difficult. Recent data show MDM to contain 20 picocuries (pC)/gram of calcium and hand deboned meat to contain 19 pC/gram of calcium. Using the ERDA household model, the amount of calcium from meat consumed per year per person is 12.6g.

Assuming 12 percent of the meat is MDM, a person would ingest 30 percent more strontium-90 than if consuming no MDM. A 100g wiener containing 12 percent of MDM would provide .89 pC/gram of calcium as opposed to .009 pC/gram of calcium in a regular meat frank.

The strontium-90 content of milk has dropped from 32 pC/gram of calcium in 1964 to 5 pC/gram of calcium in 1976. Dr. Spencer said the latest information on strontium-90 showed a daily consumption of 3.2 pC excluding milk. Dr. Engel said the total daily intake is now 8.3 pC of strontium-90 and that a 100g wiener with 12 percent MDM would be expected to provide 10 percent of the total intake. Even though the level of strontium-90 in a diet with MDM appears far below any hazardous level, consumption data are needed to determine the total body burden for various age groups.

Arletta Beloian described the status and needs of the food consumption survey studies. She stated that possibly many things should be investigated including: (1) the average diet, (2) the 90th percentile for each of the foods MDM is used in, and (3) the total diet. Presently, the 1965 USDA data for intakes of individuals are being used and updated by adding data for the frequency of eating over a 2-week period, as obtained from the Market Research Corp. of America. More data are needed for fluoride, strontium-90, etc. in foods. However, a gap still exists in information on levels of fluoride and strontium-90 in the total diet.

Zinc, Selenium, Iron, and Magnesium as Nutrients - Dr. Fox reported that from the data generated so far, there appears to be a little less zinc in MDM than in hand deboned meat. However, with the addition of MDM to the total food supply, an overall net gain in zinc would likely result. This gain is considered a plus because of the less than adequate levels of zinc believed to be in the food supply. The availability of zinc may be lowered by high levels of calcium in MDM, but the level of calcium was not thought high enough to make a difference.

The amount of selenium in bones is very small and would not provide an incremental increase in the diet.

The iron content is higher in MDM than in hand deboned meat. Some of the additional iron may come from the machinery, and this was to be further investigated. Most of the iron would be heme iron which is very available. Also, studies on mechanically deboned turkey have shown the iron to be available. One potential area of concern is the finding in Canada that bone meal used in flour was believed to cause anemia.

The magnesium content is a little less in MDM than in hand deboned meat.

The cadmium content of MDM is not appreciably different from hand deboned meat.

Lipids--Nutrition and Health Aspects - Dr. Judd reported that the lipid content is generally higher in MDM than in hand deboned meat and could reach levels of 50-60 percent. When MDM is used in products, the question arises whether the spectrum of fat will change. The limited amount of data now available show that cholesterol differences would be slight. There is also no evidence that bone marrow will add substantially more cholesterol to products in which it is contained.

Concern was expressed about the additional fat that would be harvested and made available for the diet. It was recommended to limit the fat content of MDM as well as the finished product. It was also proposed to put a limit on the ratio of fat to protein.

Dr. Combs strongly supported the concern for the increase in dietary fat available, but questioned if this product should be singled out. He agreed that restrictions should be placed on the amount of fat in MDM.

Considerable discussion ensued over the concept of "harvesting" fat, but it was agreed that this was probably outside the scope of the committee, and the efforts of the group should be directed toward the quality differences in the lipids.

The question of lipid rancidity was raised. Though available data are inconclusive, it is generally believed the MDM is more susceptible to rancidity.

Protein and Protein Quality - Mr. Fried related the intent of the proposed regulations to maintain product of high quality by requiring nutritional parameters similar to those of the trimmings being replaced. The difficulties in using rat feeding studies to determine protein quality were mentioned especially in relation to compliance. As a result, most of the data of protein quality have been derived from amino acid profiles. The subcommittee was of the opinion that PER determinations are still the best measure of protein quality. However, it was agreed that, for a specified time after any regulation is promulgated, it would be acceptable to use the percentage of essential amino acids in the total protein as an indicator of protein quality. At the end of the period, rat feeding studies would have to be used unless better methodology is developed or a significant useful relationship between PER and amino acid profile can be established. The regression equations permitted earlier as a third alternative or determining protein quality would not be used during this interim period because complete amino acid profiles would be more useful in evaluation. PER determinations and amino acid profiles are presently being conducted on 31 samples of MDM.

Dr. Forbes reiterated the desire for PER determinations until better methodology is obtained. Also, a period of time to accept amino acid profiles should be of reasonable duration, preferably on the order of one year.

Dr. Naghski reported that the limited amino acid data he had evaluated revealed beef and MDM to have fairly equivalent profiles.

Chlorinated Hydrocarbon Residues Dr. Engel reported that the chlorinated hydrocarbons DDT, HCB, lindane, BHC, heptachor epoxide, and dieldrin were determined in MDM and found to be within the tolerances set by FDA and EPA and to be of the same profile as regular fat.

Dr. Nelson warned that the data on hand deboned meat may be misleading since the hand deboned meat analyzed is not representative of the trimmings which would be replaced by MDM.

Dr. Kolbye summarized briefly the day's proceedings. The potential hazards to health appear mostly to have impact on infants, young children, and those individuals with renal disease. The nutrients of primary concern are fluoride and lead; strontium-90 may need some reflection. The quality of the MDM lipids should be determined and consideration should be given to rancidity problems and the proposal to adopt a fat limit on MDM. The need for extensive food consumption data is apparent. The cost of the computer time involved may dictate some USDA support.

The question of using 90th percentile figures for consumption data and metal concentration was raised. It was suggested that the high percentile figures be used, but then the interpretations of results be adjusted to reflect reality.

Seeking expertise from other qualified persons on relevant issues was advised. If presentations to the group by nonmembers of the committee are found necessary, Dr. Kolbye, Dr. Nelson, or Mrs. Murphy should be notified.

Drafts of reports should be sent to Mrs. Murphy by January 7, for circulation to other members of the committee. The next meeting is scheduled for Friday, January 21, 1977.

ATTENDEES AT THE SECOND MEETING OF THE
SELECT PANEL ON THE HEALTH AND
SAFETY ASPECTS OF MECHANICALLY DEBONED MEAT

Ms. Arletta Beloian, Food and Drug Administration
Mr. Bill Bloom, Animal and Plant Health Inspection Service
Mr. Ron Brewington, Meat and Poultry Inspection Program
Dr. William Burke, Meat and Poultry Inspection Program
Dr. Joginder Chopra, Food and Drug Administration
Dr. Gerald Combs, National Institutes of Arthritis, Metabolism, and Digestive Diseases
Mr. Bill Dennis, Meat and Poultry Inspection Program
Dr. Ronald Engel, Meat and Poultry Inspection Program
Dr. Allan Forbes, Food and Drug Administration
Mr. Irwin Fried, Meat and Poultry Inspection Program
Dr. M. R. S. Fox, Food and Drug Administration
Dr. Joseph Judd, Agricultural Research Service
Dr. Albert Kolbye, Food and Drug Administration
Dr. Kathryn Mahaffey, Food and Drug Administration
Dr. Eugene Morris, Agricultural Research Service
Ms. Elizabeth Murphy, Meat and Poultry Inspection Program
Dr. Joseph Naghski, Agricultural Research Service
Dr. Merlin Nelson, Meat and Poultry Inspection Program
Dr. Samuel Shibko, Food and Drug Administration
Mr. Wertice Smith, Meat and Poultry Inspection Program
Dr. Herta Spencer, Veterans Administration
Dr. John Spaulding, Meat and Poultry Inspection Program

MEMBERS OF USDA COMMITTEE ON FOOD SAFETY ATTENDING AS OBSERVERS

Mr. Bernard Alexander, Food and Nutrition Service
Mr. Robert Brown, Animal and Plant Health Inspection Service
Mr. William Manley, Agricultural Marketing Service
Ms. Opal Mann, Extension Service
Ms. Virginia Mewis, Animal and Plant Health Inspection Service
Mr. Robert Nelson, Agricultural Research Service
Mr. David Patton, Agricultural Marketing Service
Mr. Tony Staed/for Nancy Steorts, United States Department of Agriculture
Mr. Steve Zobrisky, Cooperative State Research Service

SUMMARY OF THE THIRD MEETING OF THE
SELECT PANEL ON THE HEALTH AND
SAFETY ASPECTS OF MECHANICALLY DEBONED MEAT

The third interagency meeting on the health and safety aspects of the use of mechanically deboned meat (MDM) convened at 9:15 a.m. on Friday, January 21, 1977. A list of the attendees of the meeting is attached. Copies of the subcommittee chairmen's reports are available from Mrs. Murphy if needed.

Dr. Kolbye briefly summarized that the bone particle size of MDM and its digestibility properties are such that any concerns for health hazards are not warranted. Dr. Engel further confirmed this by reporting that examination of rats fed a diet of MDM for PER determinations revealed no abnormalities or penetration of bone particles in the stomachs or intestinal tracts. An occasional partially digested bone particle was found in the duodenum, but not beyond. Both a control and a study rat had exhibited a case of enteritis.

Dr. Spencer reported that there was no additional information on calcium. Fourteen outside consultants had been contacted concerning calcium as a possible health hazard. Thirteen stated that the additional calcium would be beneficial. One consultant was against the use of MDM because of the belief that better sources of calcium are available. Three consultants made the unsolicited comment that calcium content labeling would be desirable for those persons on low calcium diets.

Dr. Mahaffey indicated that the current intake of lead for adults is approximately 250 mcg/day, which is significantly lower than the WHO recommended tolerance level of 430 mcg/person/day. The most recent recommendations on the permissible levels of lead intake for children and infants are considerably lower than for adults. In her evaluation of the impact of lead on the diet, it was found that the amount of MDM consumed was more important than the lead content of MDM. Beyond this she was uncertain as to the significance of her evaluation because of the discrepancies being found between USDA and FDA data on the lead content of hand deboned meat and MDM.

At this juncture, Dr. Ken Boyer, Division of Chemistry and Physics, Bureau of Foods, FDA, presented data showing an approximate five to seven fold discrepancy between USDA and FDA analytical data for lead. The reason given for the higher USDA values was use of an analytical method that does not eliminate the background interference from calcium primarily, but also from sodium and potassium. USDA had used the atomic absorption procedure without subtracting all of the background interference, whereas FDA's lower values were based on the anodic stripping voltammetry technique. Dr. Boyer also expressed his concern that substantially higher values of arsenic, antimony, boron, and titanium were

being found in MDM than in hand deboned meat. Dr. Engel confirmed that analytical discrepancies are existing between WARF, FDA, and USDA; WARF is finding the lowest values for lead.

The status of the progress of the committee in view of the suspect USDA values for lead was discussed at great length. It was reiterated that the most critical question is the increased average intake of lead if hand deboned meat is replaced by MDM. The possibility of using a correction factor or an extrapolation approach from the hand deboned meat data was discussed but was not considered viable. Alternate methodology that is less time-consuming than the anodic stripping technique was also discussed without reaching a general consensus. Consequently, it was felt that the need to reanalyze may be the only solution to the dilemma. However, very few laboratories in the United States have the equipment and expertise to determine lead in MDM by anodic stripping. A subcommittee consisting of Dr. Spaulding, Dr. Mahaffey, Dr. Boyer, Dr. Morris, and Dr. Engel was appointed to further discuss this problem, with emphasis on methodology, sampling population needed and overall approach in view of time constraints.

As a result of the revelation of the discrepancies in the lead analyses, the usefulness and validity of market basket surveys, literature values for lead, clinical data, etc. were questioned.

Mrs. Beloian then described in some detail the computer analyses being done to determine consumer exposure to various metals from foods containing MDM. The importance of using 90th percentile consumption times 90th percentile MDM content values was questioned because so few of the population would be affected.

Dr. Mahaffey related that attempts are being made to reduce the overall lead content as well as other toxic metals in the diet, and that MDM provides more lead than canned foods. Presently, approximately 10 percent of the U.S. population has elevated lead values according to HANES.

Dr. Fox gave the results of the cadmium study. Only the 90th percentile MDM intake 90th percentile cadmium concentration gave increases of cadmium intake considered significant, primarily for infants. It was pointed out the recommended acceptable daily intakes for cadmium are more tentative than lead. Dr. Shibko also said that one study on human infants suggests that cadmium is more readily absorbed, but also more readily excreted.

Again the validity of any conclusion was questioned because of analytical results of FDA showing cadmium levels one-tenth as high as USDA's for the same reasons as explained for the lead data. The cadmium levels found by USDA were also questioned because radioactive tagging studies have shown that very little ingested cadmium ends up in the bone.

Dr. Fox also reported there should be little change in the overall intake of iron, selenium, zinc, and magnesium in the diet as a result of the use of MDM.

Dr. Spencer updated her earlier report on the fluoride content of MDM as a possible health hazard. She related that the fluoride intake recommended by the American Dental Association was .5 mg/day up to three years of age and that fluoride analyses of infant foods have shown that from six weeks to six months, infants would consume without fluoridated water more than this recommended level. On this basis and inasmuch as the literature contains contradictory information on the fluoride intakes of infants, she would recommend MDM not be allowed in infant foods.

The discussion that ensued pointed up the fact that there is an apparent trend of less infant food being used because of the increased interest in blending foods, including adult type foods in the home. Also mentioned was the fact that it is important to realize that by age two, most infants are consuming table foods. As a result, the importance of adult foods in the diets of infants and children must be considered. It was suggested that the fluoride analytical data accumulated should be utilized in the computer evaluation so that a better position could be reached for approving or condemning MDM.

It was generally agreed that the lead and fluoride problems were the main issues and should be the focal points of the committee's attention.

Dr. Nelson stated that if it was recommended that MDM should not be allowed in infant foods, the following alternatives would be considered:

1. To lower the percent of MDM used in all products.
2. To restrict MDM usage to certain products.
3. To disallow use.
4. To provide labeling with precautions.
5. To restrict calcium levels more.

Dr. Kolbye briefly reaffirmed the charge of the committee to evaluate only the health and safety aspects of MDM. He felt that if the fluoride hurdle could not be overcome, there was little need to attempt the lead.

The possibility of a 5 percent limitation on the use of MDM for all products was discussed as a likely approach.

The USDA is to decide on the option it wishes to take and will inform Mrs. Belgian so that, if necessary, the appropriate computer evaluation can be conducted.

Drs. Judd and Combs stated that they could make no further evaluation on lipids until more data are forthcoming on cholesterol and fatty acids.

Dr. Naghski had questions requiring clarification on the PER data obtained a few days before the meeting. With reservations as to whether the PER's might be low, he approved Mr. Fried's report on protein and protein quality.

It was agreed that another meeting was necessary and will be held on March 18.

ATTENDEES AT THE THIRD MEETING OF THE
SELECT PANEL ON THE HEALTH AND
SAFETY ASPECTS OF MECHANICALLY DEBONED MEAT

Ms. Arletta Beloian, Food and Drug Administration
Dr. Kenneth Boyer, Food and Drug Administration
Mr. Ron Brewington, Meat and Poultry Inspection Program
Dr. Joginder Chopra, Food and Drug Administration
Dr. Gerald Combs, National Institutes of Arthritis, Metabolism, and Digestive Diseases
Mr. Bill Dennis, Meat and Poultry Inspection Program
Dr. Ronald Engel, Meat and Poultry Inspection Program
Dr. Allan Forbes, Food and Drug Administration
Dr. M. R. S. Fox, Food and Drug Administration
Dr. Joseph Judd, Agricultural Research Service
Dr. Albert Kolbye, Food and Drug Administration
Dr. Kathryn Mahaffey, Food and Drug Administration
Dr. Eugene Morris, Agricultural Research Service
Ms. Elizabeth Murphy, Meat and Poultry Inspection Program
Dr. Joseph Naghski, Agricultural Research Service
Dr. Merlin Nelson, Meat and Poultry Inspection Program
Mr. Bob Nelson, Agricultural Research Service
Mr. Bob Norton, Animal and Plant Health Inspection Service
Mr. Dave Patton, Agricultural Marketing Service
Dr. Samuel Shibko, Food and Drug Administration
Ms. Evelyn Spindler, Extension Service
Mr. Wertice Smith, Meat and Poultry Inspection Program
Dr. John Spaulding, Meat and Poultry Inspection Program
Dr. Herta Spencer, Veterans Administration

SUMMARY OF THE FOURTH MEETING OF THE
SELECT PANEL ON THE HEALTH AND SAFETY ASPECTS
OF THE USE OF MECHANICALLY DEBONED MEAT *

SESSION I

The fourth meeting of the select panel on the health and safety aspects of the use of mechanically deboned meat (MDM) convened at 9:30 a.m. on Thursday, July 7, 1977. A list of the attendees of the meeting is attached.

Dr. Kolbye asked for new developments in the area of bone particle size. Dr. Engel reported that electro-microscopic photographs had been received from the Energy Research and Development Administration, but that the photographs revealed essentially the same information as before. Dr. Kolbye reiterated that he did not anticipate any problem with bone particles and received an expression of agreement from the panel members.

Dr. Spencer related that there was very little new concerning the calcium content of MDM. Using the consumption data afforded by FDA, calculations indicated that the intake of meat products which contain MDM is so low that the additional calcium ingested is minimal and would not be a problem. Dr. Spencer did state that the addition to the diet of the calcium in MDM would be beneficial especially to the large segment of the population that has an inadequate or suboptimal calcium intake.

Dr. Chopra commented that this additional calcium would also be beneficial in view of the high phosphorus content of the diet. Dr. Spencer added that the calcium:phosphorus ratio in MDM is 1.4:1, which is desirable.

Dr. Nelson asked the question of whether or not the concerns aired in earlier sessions on the need for calcium labeling still existed. Dr. Spencer replied that those concerns were expressed before the consumption study data were available and that even for the kidney stone formers, the additional calcium is so small that labeling is not necessary.

Dr. Chopra expressed concern for persons who are on diuretics, such as thiazides, which tend to bind calcium, as well as patients with chronic kidney failure and felt that labeling would be helpful.

Dr. Kolbye viewed this as more of a potential health problem with ramifications beyond the potential problems posed by MDM.

Dr. Spencer stated that she did not believe that the users of thiazides would present a problem since the intestinal absorption of calcium is

* A verbatim transcript of this meeting is on file with the Food Safety and Quality Service, Information Division.

not affected by their use. She added that the chronic kidney patients already have calcium intakes that are much too low and the calcium from MDM would be desirable for these patients.

Dr. Chopra believed in general that nutrition labeling would be useful for any controlled diet.

Some questions were raised about the quality control of MDM. It was pointed out that the possibility of obtaining large bone particles from the machinery is very unlikely. On occasion, the screens do break, but with such an explosive force that it is obvious that something is wrong. The calcium content, it was clarified, would be monitored and, at the very minimum, the product would be monitored as any other product for which problems might be encountered.

Dr. Spencer then reported her conclusions, based on the consumption data with MDM constituting 20 percent of the meat block, that the additional fluoride expected in the diet of all age groups would be very low and would have to be considered a harmless, negligible amount. For example, the added fluoride intake for infants, 0-2 years, would be .05 milligrams per day; for children, 3-5 years, .07 milligrams; and for children, 6-12 years, .13 milligrams.

Dr. Chopra, agreeing that the levels of additional fluoride are small, commented that since an excess of fluoride intake apparently already exists for younger age groups, more fluoride should not be added regardless of the amount because the bodies are already overburdened.

Dr. Spencer replied that not only is there a lack of agreement among researchers on the total intake of fluoride, but also there are differences of opinion at the American Academy of Pediatrics as to the what the actual fluoride intake of infants should be.

Dr. Kolbye asked Dr. Spencer to rearticulate the information on fluoride intake of young children in terms of total anticipated intake without MDM versus total anticipated intake with MDM. She replied that according to her studies, infants up to age six months would have an intake of 1.2 milligrams of fluoride per day and 50 micrograms of fluoride per day would then be added from MDM based on the consumption studies. She also stated she would not expect the intake of fluoride of children to be much different after six months.

Mrs. Murphy explained the basic makeup of the consumption data and pointed out the data are given in terms of eaters of the various products rather than total population. The data are adjusted for frequency of eating using the MRCA data. After some discussion Dr. Spencer clarified that the data related above represented 90th percentile intakes times 90th percentile population.

There was also some discussion as to whether or not the consumption data included products that contain mechanically deboned chicken, which if used in combination with MDM might pose a potential problem in terms of fluoride intake. The consumption data did not include products containing mechanically deboned poultry.

Dr. Nelson affirmed that mechanically deboned chicken has to be addressed as a separate issue since it is under a separate Act and different set of regulations.

The pursuant discussion centered around the possibility of the additive effect of infants and young children consuming consistently high-fluoride beef products in addition to mechanically deboned chicken products, and being in an area containing fluoridated water. Inasmuch as there were a number of unanswered questions about the expected exposure of infants to fluoride, a recommendation was made by Dr. Fox that until more is known it would be prudent not to permit mechanically deboned meat in baby and junior foods.

Dr. Kolbye asserted that if any decision or recommendation is made that MDM be added to or restricted from baby foods that hard data are needed as well as good documentation. Data on the level of mechanically deboned chicken used in baby foods and the consumption levels in 1965 were considered as useful in acquiring an appreciation for the current intake of mechanically deboned chicken and thus, the fluoride intake. Unable to obtain any definitive information, the panel moved on to the lipid content of MDM.

Dr. Judd reported that the spectrum of the lipid content including cholesterol content appeared the same as in other red meat products. Both Dr. Judd and Dr. Combs expressed the desire to control the amount of fat entering the diet and to avoid the harvesting of fat through MDM.

It was then explained by officials of the USDA that the proposed regulation imposed controls on MDM, limiting the fat content of MDM to 30 percent and MDM for processing to 50 percent and placing minimum protein levels of 14 percent and 10 percent respectively on these MDM products. Furthermore, it was pointed out that many products in which MDM may be used have their own finished product fat content restriction. Aside from this, manufacturers themselves impose nutritional parameters in order to maintain a product of the quality wanted. The use of MDM, it was pointed out, would not change this.

Dr. Combs expressed concern over the 50 percent limitation being placed on MDM for processing because he considered this level as being out of reason in relation to normal manufacturing practices. He stressed that good manufacturing practices be followed in deriving MDM.

Dr. Judd reminded the group of the restraining order, which addressed the long term cardiovascular effects of ingesting MDM. Dr. Chopra also brought up the question of saturated fat in the diet.

Dr. Kolbye expressed the view that the panel was not the proper forum for such discussions and again these were issues much more widespread than MDM which represents only a very minor component in terms of the total addition of animal fat to the diet. Dr. Nelson added the USDA would have a difficult time finding the legal authority to restrict the harvesting of fat, but could restrict the fat content of individual products.

Dr. Fox substituting for Dr. Mahaffey then addressed the potential lead problem and reported that such small amounts are present in mechanically deboned meat that the total intake of infants and adults is negligible.

Dr. Boyer traced the history of the problems that had been encountered in the lead analyses and concluded that the high values previously obtained were due to interference from the calcium present. The FDA and USDA analyses are now in good agreement.

Dr. Kolbye made it clear for the record that the panel was aware of the problems of lead poisoning in bone meal, but that MDM poses no such problem because of the low levels of lead present.

Dr. Fox then reported that cadmium had been considered a potential problem much as lead because of the high values being found due to the interference of calcium. However, the most recent analytical data show cadmium to be nondetectable. Even if found at the detectable level, she believed, there would be no problem.

Dr. Fox with Dr. Morris' concurrence cleared zinc, iron, nickel, and copper as posing no potential health problems, and added that though the zinc levels in MDM are slightly lower than red meat, any increase in dietary zinc from the use of MDM would be desirable. Dr. Morris added that the iron in MDM might also be of some slight benefit.

The question of iodides posing a problem was posed by Dr. Kolbye but dismissed.

Dr. Engel restated his previous conclusion that the strontium-90 level in MDM is well below the radiation protection guides developed by the Federal Radiation Council. The data, even if maximized, revealed that strontium-90 intake from MDM would be insignificant.

Dr. Fox then stated that selenium, which was being found in MDM at concentrations comparable to hand-deboned meat, would be no problem.

The question of arsenic levels was raised but dismissed as a problem in MDM because of the low levels found in mechanically deboned poultry.

Dr. Naghski reviewed the updated report of Mr. Fried's on the protein quality of MDM. A comparison of the PER and calcium content of the same samples revealed that with two exceptions the levels of calcium being found would lead to PER's of 2.4 or above. In plotting protein versus PER, it was shown that the minimum protein of 14 percent proposed for MDM would result in PER's of 2.5 $\pm$ .1 or .2. He concluded that with the nutritional parameters proposed he could not visualize any problem from a nutritional point of view.

Dr. Naghski then addressed the alternate possibility of using the percent of essential amino acids in MDM as an index of quality. He hesitated to say that this is a reliable index of the protein quality and expressed concern that the tryptophan content was not determined on these samples. However, he agreed that the analyses for tryptophan would double the cost and though he believed the tryptophan content to be a good indicator of the nutritional character of MDM, he conceded that the data are not sufficient to justify a tryptophan determination as a substitute for the amino acid profile.

Dr. Nelson summarized that the PER is the method of choice to determine protein quality, but was hoping that the percent of essential amino acids could be used as an alternative since this determination is less expensive. He did believe that PER determinations in conjunction with a determination of the percent of the essential amino acids would give a good handle on the protein quality.

Dr. Naghski commented that he was not concerned about the collagen content of MDM, estimated to be around 20 to 30 percent (about the same as many cuts of meat), because collagen is supplementary to other proteins and increases the nutritional value overall.

Dr. Kolbye concluded, with the panel's concurrence, that the protein quality of MDM is as satisfactory as other sources of meat and is equivalent to good quality protein.

SESSION II

The second session of the fourth meeting of the Select Panel on the Health and Safety Aspects of the Use of Mechanically Deboned Meat convened on Friday, July 8, at 11:00. The afternoon before and the morning had been spent working in subgroups reviewing drafts and references for the final report.

The issue of chlorinated hydrocarbon residues in MDM was considered and quickly dismissed as presenting no problem.

Dr. Engel then discussed his revised report on strontium-90. Using the new data on estimated consumption of MDM, and taking the average MDM intake instead of the 90th percentile, since all the radiation guides on strontium-90 intake are based on averages, an increase in picocuries of 1 percent per year would be expected. This increase was considered very insignificant. Using calculations based on millirems, the results also were insignificant, revealing that the exposure from MDM might approach .05 millirem of strontium-90 per year, while the new EPA drinking water standards allow 4 millirems per year. With suggestions for clarification of the wordings of some statements, the report was accepted.

Dr. Fox summarized her findings that the concentration of zinc in skeletal meat from beef and from pork is essentially the same as in MDM. Dr. Kolbye stated, and Dr. Fox concurred, that there is no evidence that the use of MDM would adversely affect the bioavailability of zinc from other sources of the diet. The draft of the zinc report was accepted by the Panel.

Dr. Spencer then went through her report on calcium, reemphasizing many of the salient points mentioned at previous sessions. She concluded that the amount of calcium obtained from consuming MDM is not significant although in general the small levels ingested may be beneficial. She stated that appropriate labeling of the calcium content would be useful to certain groups of individuals who must be maintained on a low calcium diet, but was not certain as to what the most appropriate means of labeling should be. There was considerable discussion as to whether quantitative labeling was needed or if the mere listing of MDM as an ingredient, as such, would be an adequate means of alerting health advisors and individuals who would need to know about the presence of MDM.

The panel moved on to the potential problems of fluoride. The statement in Dr. Spencer's draft report that children in high fluoride areas should not consume MDM was then the subject of much discussion. Dr. Spencer explained that little is known about the fluoride intake of children and one has to be concerned if these children live in areas where the water contains high levels of fluoride, e.g., 4-8 ppm. But

she believed that, based on the consumption data, the added fluoride from MDM would be very minimal. Putting the situation into perspective, Dr. Spencer stated that the consumption of a tuna fish sandwich, or a soft drink, or a glass of iced tea would result in higher intakes of fluoride than would eating two frankfurters containing 20 percent MDM in the meat block. Dr. Kolbye noted that there were public health implications concerning fluoride consumption whether MDM was used or not and also asked the Panel members if they thought the amount of fluoride in MDM might be enough to push children over the threshold and into problems of excess consumption. He also stated his own conclusions, which were that the amount of fluoride which would be consumed through use of MDM would be relatively insignificant.

The question of the levels of fluoride needed to cause mottling in teeth was raised. There was some disagreement on the levels needed. Dr. Chopra read from a WHO publication a statement that mottling of teeth of young children less than eight years of age can occur if the fluoride in the drinking water exceeds 1.4 to 1.6 ppm, and that even at levels of 1 ppm some perceivable change can occur. It was noted that EPA recommends a fluoridation level of 1 ppm and will tolerate 2 ppm. It was later discovered that these amounts are the subject of current litigation. Dr. Chopra cited a reference from the Committee on Nutrition of the National Academy of Pediatrics stating that beneficial effects of fluoride are noted at levels of 1.5 to 2.5 milligrams per day, and a degree of tooth mottling is observed when the ingestion exceeds 3 milligrams per day from all sources. She also read that the daily fluoride intakes of children to 12 years of age were: .83 milligrams (1-3 yrs), 1.11 milligrams (4-6 yrs), 1.38 milligrams (7-9 yrs) and 1.73 milligrams (10-12 yrs), all of which were far below the 2.5 mg level. Dr. Kolbye pointed out that the 50 or 60 micrograms expected from MDM would be rather small in proportion. He added that there are other competitive sources of fluoride in the diet and that MDM in comparison does not represent a substantial contribution.

With this information, the panel was unanimous in believing that the amount of fluoride expected in the diet from MDM would be insignificant in posing any potential health problem to children.

Dr. Spencer reemphasized her recommendation concerning the use of MDM in infant and junior foods. She stated that since long-term data are not available, and since MDM may vary in different localities, MDM should not be incorporated in baby or junior foods at present. The panel agreed with the recommendation but many members remarked that the recommendation is primarily based on lack of information, not evidence of a hazard, and should be subject to further evaluation as data are gathered.

Dr. Judd then reported that the subcommittee on lipids consisting of himself and Dr. Combs concluded that since data presently available show the lipid spectrum of MDM to be comparable to other meat products, there

does not appear to be any special problem with regard to effects of MDM use on cardiovascular systems. However, since MDM is a product that could have a high fat content, there should be limits placed on the fat content of MDM as harvested and on fat content of products in which MDM is used. This recommendation, they believed, was incorporated adequately in the proposed regulation. The committee concurred with the draft report and moved on to a discussion of particulates.

Dr. Engel reported that after rat feeding studies, made to determine PER's of MDM, the rats were sacrificed and the intestinal tracts examined from the oral cavity to the anus. In summary, no significant histo-pathological alterations in any of the 120 animals studied were found which could be attributed to any dietary factor.

Dr. Kolbye added that the photographs taken of the bone particle size did show some variance from study to study which he thought could be related to the machinery used. The photographs also showed that many of the larger particles were aggregates of smaller particles, which were easily broken up. The solubility appeared good from the indirect studies conducted using human gastric tubes. Also FDA has data showing that the calcium in bone meal is readily absorbed. In Canada and Newfoundland bone meal is used as a supplement to the diet. The Bureau of Foods, FDA, also has documented cases that ingestion of glass particles in the size range of the bone in MDM represents no human hazard. Studies with dogs indicated no health problems when glass fragments were ingested. In addition, Dr. Kolbye stated that by the time the lower colon is reached, one would expect little residue to be left from the bone particles.

Addressing a comment received on the proposed regulation, Dr. Kolbye commented that in terms of the various tests performed, there is nothing to indicate a problem with carcinogenicity.

The question was raised if the particle size would be restricted by regulation. Everyone agreed that there should be some limit. Mr. Fried recommended that an appropriate approach would be to refer to the docket on the panel's report showing the particle sizes desired and to restrict by regulation the particle size within the guidelines of good manufacturing practices.

Dr. Kolbye received concurrence from Dr. Fox and the other members of the panel that based upon the information available and Dr. Mahaffey's memo there was no lead problem.

Dr. Fox concluded that the amounts of cadmium in MDM are so small as to be of no public health significance. Dr. Spencer added that you would expect this since cadmium tends to localize in the kidney and liver and not the bone. The cadmium report was unanimously accepted.

Dr. Kolbye reconfirmed the concurrence of the panel in the first day's proceedings that arsenic is not a problem.

The question of labeling for calcium was raised, with concern expressed by Dr. Chopra that labeling of MDM as only an ingredient would not provide information needed by some individuals about the level of calcium present. Dr. Kolbye offered the concept that if MDM appeared as an ingredient, this should provide insight to the potentially higher than normal calcium content of the food product. This concept was agreed on and the recommendation that MDM be labeled as an ingredient received concurrence from the group.

Dr. Fox reported that the selenium concentrations in MDM were considerably lower than found in lean beef. She also found nothing in the literature to indicate that selenium concentrates in the bone. Selenium was then considered a nonissue.

Iron and copper were also determined by the panel not to pose a potential problem. It was mentioned that the additional amount of iron from MDM would be in the order of 2.5 percent of the total iron intake for adults.

The group concurred that the approximate cobalt contribution from high level ingestion of MDM would not be a problem. It was estimated to represent 1 percent of the expected dietary intake of cobalt.

Nothing was added to the previous report on protein quality and it was accepted by the group subject to certain editorial comments. One change mentioned was that the essential amino acids would be compared to the total amino acids and not to total protein because of the consistent figures that resulted.

At this point Dr. Kolbye requested the group to express any dissents, disagreements, or clarifications.

Dr. Spencer commented that, if MDM is labeled as an ingredient, steps should be taken to inform the medical community of what this means in terms of calcium and fluoride content. All agreed.

Dr. Kolbye stated that the group should recommend that if the fluoride situation changed MDM should be evaluated.

Dr. Nelson then asked for the group's thoughts and recommendations on a number of loose ends. The question of microbiological problems was raised but the consensus of the group was there was nothing unique about MDM and this should not be a concern if good manufacturing practices, quality control, etc., are employed. Pyorrheadentitis, from the impaction of fine particles between gums and teeth, or between the teeth, had been mentioned in a comment. Dr. Kolbye responded that the particle

size of MDM is of the same nature as many other types of food particles and no hazards should be expected. An article was alluded to that discussed the concentration of tetracyclines in bone marrow. Dr. Kolbye did not anticipate any problems but promised to have the Division of Toxicology, FDA, evaluate the issue. The question of mercury residues was dismissed since mercury tends to concentrate in soft tissues not in bones.

At that time, the meeting was closed and the panel adjourned, except for the follow-up responsibilities of finishing the various portions of the final report.

ATTENDEES AT THE FOURTH MEETING OF THE
SELECT PANEL ON THE HEALTH AND SAFETY ASPECTS
OF MECHANICALLY DEBONED MEAT

SESSION I

Dr. Ken Boyer, Food and Drug Administration
Mr. Ron Brewington, Meat and Poultry Inspection Program
Mr. Sid Butler, Deputy to the Assistant Secretary for Food and Consumer Services
Dr. Joginder Chopra, Food and Drug Administration
Dr. Gerald Combs, National Institutes of Arthritis, Metabolism, and Digestive Diseases
Mr. Bill Dennis, Meat and Poultry Inspection Program
Dr. Ronald Engel, Meat and Poultry Inspection Program
Mr. Irwin Fried, Meat and Poultry Inspection Program
Dr. M. R. S. Fox, Food and Drug Administration
Dr. Joseph Judd, Agricultural Research Service
Dr. Albert Kolbye, Food and Drug Administration
Dr. Eugene Morris, Agricultural Research Service
Ms. Elizabeth Murphy, Meat and Poultry Inspection Program
Dr. Joseph Naghski, Agricultural Research Service
Dr. Merlin Nelson, Meat and Poultry Inspection Program
Dr. Herta Spencer, Veterans Administration
Mr. Keith Steele, Meat and Poultry Inspection Program

ATTENDEES AT THE FOURTH MEETING OF THE
SELECT PANEL ON THE HEALTH AND SAFETY ASPECTS
OF MECHANICALLY DEBONED MEAT

SESSION II

Mr. Ron Brewington, Meat and Poultry Inspection Program
Dr. Joginder Chopra, Food and Drug Administration
Mr. Bill Dennis, Meat and Poultry Inspection Program
Dr. Ronald Engel, Meat and Poultry Inspection Program
Mr. Irwin Fried, Meat and Poultry Inspection Program
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